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Connecticut Medicine

The Journal of the Connecticut State Medical Society

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Special Issue: Lyme Disease

Matthew L. Cartter, M.D., Guest Editor

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Reye's Syndrome in an Adult

BARRY A. EAGEL, M.D., BERNARD VINOSKI, M.D., AND DAVID KRUGMAN, M.D.

ABSTRACT—There have been over 3,500 cases of Reye's syndrome reported to the CDC since 1973. The temporal use of aspirin with a prodromal viral illness has been statistically associated with the etiology of the syndrome. Reye's syndrome presents as an acute progressive encephalopathy with varying levels of coma and normal cerebrospinal fluid (CSF). Hepatic transaminases are elevated, and the serum aspartate aminotransaminase (AST) is usually elevated three to 30 times normal. Histological changes on liver biopsy are characterized by microvesicular intrahepatocyte lipid deposition, which is rarely found in other diseases.

The syndrome has rarely been reported to occur in adults over 18 years old. We report the 25th case of Reye's syndrome occurring in an adult, which initially presented as acetaminophen toxicity but was shown to be Reye's syndrome on histological examination of the liver.

REYE'S syndrome (RS) is a well characterized clinical entity consisting of a prodromal viral illness, followed in three to five days by vomiting, altered levels of consciousness, noninflammatory encephalopathy, and hepatic dysfunction. There have been over 3,000 cases reported to the Centers for Disease Control since 1973.¹ However, there are only 20 previously reported cases in the literature of occurrence in the adult population. Aspirin (acetylsalicylic acid) ingestion has been statistically associated with prodromal viral illness in the etiology of Reye's syndrome. We report a case of adult RS which was complicated by concomitant acetaminophen intoxication.

Case Report

A 26-year-old white male with a history of paranoid schizophrenia and a suicide attempt with thioridazine (Mellaril) in 1982, was brought into the New Britain General Hospital Emergency Room at 7:00 p.m. on 24

January 1987 after ingestion of about 30 acetaminophen (Tylenol) tablets (9.75g) in an apparent suicide attempt. He had been taking chlorpromazine (Thorazine) and trihexyphenidyl hydrochloride (Artane), and had also been taking an unknown quantity of aspirin and bismuth subsalicylate (Pepto-Bismol) for flu-like symptoms several days preceding his admission. The patient lived alone and emergency medical technicians had been called to his home by his mother after she was unable to reach him by telephone.

In the emergency room, the patient was initially lethargic but arousable and communicative. His systolic blood pressure was 60mm Hg, pulse 120, respiratory rate 40 per minute, and his temperature was 36.1° C. Auscultation of his lungs revealed bilateral scattered rhonchi. Cardiovascular examination showed a regular rate and rhythm, tachycardia without murmurs, rubs, or extra heart sounds. Examination of the abdomen was unremarkable. Neurological assessment showed a lethargic patient but oriented and responsive to questions; he was able to move all extremities spontaneously; his pupils were dilated but reacted to light. Nasogastric aspiration revealed heme-positive fluid. Arterial pH was 6.9. The patient was intubated and a Foley catheter was inserted.

Laboratory data showed a white blood count of 30,500/ μ L with 72% polys, 19% bands. Hemoglobin was 17gm/dl, hematocrit 50.8%, mean corpuscular volume 104.6 fL. The BUN was 9mg/dl, creatinine 4.0mg/dl, glucose 85mg/dl, and serum acetone was negative. The prothrombin time was 76.1 seconds, partial thromboplastin time was 72.1 seconds. The total bilirubin was 7.7mg/dl, direct bilirubin 5.3mg/dl, alkaline phosphatase 235 IU/L, lactate dehydrogenase 7,200 IU/L, serum aspartate aminotransaminase (AST) 14,200 IU/L, and alanine aminotransaminase (ALT) 15,000 IU/L. Serum lactic acid was 28 mEq/L, phosphate 12.6mg/dl. Serum salicylate concentration was 6.3mg/dl (therapeutic range: 3 to 39mg/dl) and serum acetaminophen level was 13 μ g/ml (therapeutic range: 10 to 20 μ g/ml).

The patient was given naloxone, bicarbonate, 50% dextrose, and intravenous normal saline infusion. Intravenous dopamine was administered with his systolic blood pressure recorded at 70mm Hg; subsequently he was given norepinephrine. The patient remained anuric,

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with a systolic blood pressure of 70 to 80mm Hg. A loading dose of N-acetylcysteine was given through a nasogastric tube for suspected acetaminophen intoxication. Seven hours following admission, the patient's blood pressure fell to 50mm Hg with a pulse of 30. Attempted cardiopulmonary resuscitation was unsuccessful and the patient expired.

The autopsy findings revealed an obese white male with an estimated weight of 113 K. The lungs were edematous and had a combined weight of 2,350g. The brain weighed 1,640g and showed cerebral edema with cerebellar pressure coning. Multiple sections examined microscopically failed to reveal signs of inflammation, degeneration, or focal lesions. The liver weighed 2,540g and it was not remarkable grossly. A frozen section done at the time of autopsy did not reveal any evidence of necrosis. Microvesicular vacuolization of the liver cells was noted (see Figs. 1 and 2) and an oil-red-O stain

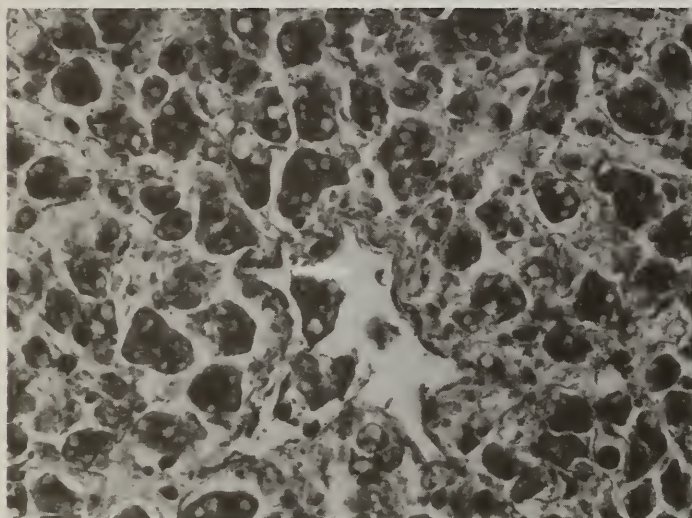


Figure 1

Microvesicular change is noted in the hepatic cells around a central vein (arrow). (Original magnification x400.)

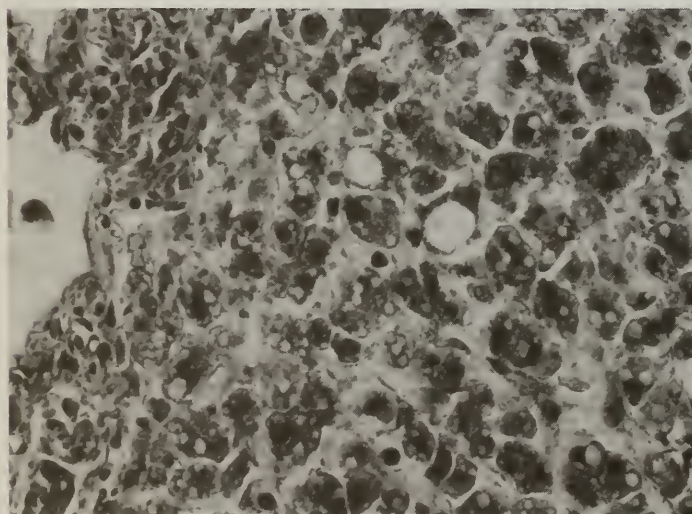


Figure 2

Microvesicular change around the portal area to the left. A few larger fat vacuoles are present, and these were uncommon. (Original magnification x400.)



Figure 3

Oil-red-O stain showing extensive fat deposition within hepatocytes, staining grey in this reproduction. (Original magnification x200.)

revealed marked diffuse fine fatty change of the liver cells (see Fig. 3). The remainder of the autopsy did not show any other significant gross or microscopic abnormalities.

A postmortem sample of heart blood showed an acetaminophen level of 53mg/L (normal therapeutic range 40 to 50mg/L). This test was performed in a separate laboratory by a different method from the one performed on the antemortem blood sample.

Discussion

The Centers for Disease Control diagnostic criteria for RS is defined as: (i) an acute, noninflammatory encephalopathy documented clinically by an alteration in consciousness and, if available, a CSF containing less than eight leukocytes per 3mm, or by a histological specimen of brain demonstrating cerebral edema without perivascular or meningeal inflammation; (ii) hepatopathy documented by either liver biopsy or autopsy considered to be diagnostic of Reye's syndrome or a three-fold or greater increase in the levels of the serum AST, ALT, or ammonia; and (iii) no other more reasonable explanation of the cerebral or hepatic abnormalities.² The patient in the present case fulfilled these diagnostic criteria, ie, the progressive encephalopathy and the diagnostic hepatic histopathological findings of microvesicular lipid deposition.

While acetaminophen toxicity was initially entertained as the differential diagnosis of his altered mental status and markedly abnormal liver function tests, this was not borne out by the therapeutic acetaminophen levels seen in both the ante- and postmortem blood samples analyzed by different techniques at different settings. Serum salicylate levels in RS are invariably reported to be within the therapeutic range.³ The pathological changes noted were consistent with RS. Acetaminophen hepatotoxicity is manifested by centrilobular necrosis.⁴ The difficulty in initial diagnosis was additionally complicated by markedly elevated AST, ALT, and bilirubin levels: 14,200 IU/L, 15,000 IU/L, and 7.7 mg/dl respec-

tively. In RS, the ALT and AST levels are usually elevated no more than three to 30 times normal and the total bilirubin rarely exceeds 1 mg/dl.¹ Acetaminophen hepatotoxicity usually causes profoundly elevated aminotransaminase levels as high as 30,000 U/L.⁵

Serum concentrations greater than 50 times normal are associated with fatal cases of acetaminophen toxicity,⁴ which usually occurs following ingestion of 200 to 250mg/kg body weight,⁶ or about 15g in a 70kg person.^{4,5}

Reye's syndrome has been epidemiologically related to salicylate use during a viral illness.⁷ The amount of salicylate ingestion is not correlated with propensity for development of RS, nor with the level of encephalopathy on presentation.⁸ The syndrome has not been reported to be secondary to salicylate intoxication. While the epidemiological pattern of prior salicylate use now appears well established by at least five studies,⁹ there are anecdotal reports in the literature of acetaminophen-induced Reye's syndrome.³ DeVivo points out that hepatic necrosis is an infrequent finding in RS, and where present, occurs in periportal areas. Acetaminophen toxicity characteristically causes centrilobular necrosis.⁵ Microvesicular hepatocyte steatosis seen in RS has similarly been noted in cases of salicylate intoxication.¹

In a matched case-control study, Halpin found a prior history of aspirin use in 97% of patients with Reye's syndrome. Sixteen percent of patients with RS in his study had taken acetaminophen prior to developing symptoms of RS, while 33% of the matched control group which did not develop RS had taken acetaminophen. Eight percent of patients with RS had a prior history of recent phenothiazine exposure, which was not statistically different from the 4% usage reported in the control group.³ The use of the phenothiazine Thorazine by the patient in this study would therefore not contribute to the observed histological findings.

Microvesicular steatosis is an uncommon pathological finding, but has been clinically reported to occur in fatty liver of pregnancy, cholesterol ester storage disease, carnitine deficiency, congenital defects of urea cycle enzymes, tetracycline toxicity, valproate toxicity, Jamaican vomiting sickness,¹⁵ Sierra Nevada de Santa Marta hepatitis,¹⁶ and in Reye's syndrome. The historical and clinical findings in this patient are most consistent with Reye's syndrome as the etiology of the hepatic histopathology.

In addition to an unknown quantity of aspirin ingestion in our patient, he was also taking bismuth subsalicylate for gastrointestinal symptoms. Viral gastroenteritis has been reported as the prodromal illness in 5% to 15% of cases of RS.¹ A United States Public Health Service study of 30 cases in 1984 reported two patients who had bismuth subsalicylate exposure prior to developing symptoms of RS, including one case for whom this represented the only salicylate exposure.¹⁰

Between 1973 and 1986, there have been 3,653 cases of RS reported to the CDC from the National Reye Syndrome Surveillance System, with a case mortality rate of 26 to 42%.^{2,17} Since 1973, there have been only 24

reported cases in the literature of patients older than 18.^{11,14,18,19} There appears to be no clinical, epidemiological, or pathological differentiation in RS diagnosed in children versus adults. Children under ten years of age have the greatest incidence of RS. Since 1980, there has been a 55% decrease in occurrence among the less than ten-year-old population, and a 33% decline in the ten to 19-year-old population.² This may reflect decreased usage of salicylates for viral illnesses in the United States. In summary, Reye's syndrome is generally considered a childhood disease. We described our experience with one adult patient in whom the diagnosis of RS was confirmed. The occurrence of RS in adults should be noted and prompt recognition of the characteristic presentation should be extended to the emergency room setting.

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Postgraduate Medicine

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Ectopic ACTH and Adrenal Myelolipoma

STEVEN C. SIEBER, M.D., NELSON A. GELFMAN, M.D.,
RONALD DANDURAND, M.D., AND FRANK BRAZA, M.D.

ABSTRACT—We describe a case of adrenal myelolipoma that occurred in a 66-year-old male with an ACTH-producing oat cell lung carcinoma. To our knowledge, this is the first case in which myelolipoma has occurred in association with ectopic ACTH-induced Cushing's syndrome. The literature is reviewed and the pathogenesis of myelolipoma is discussed.

ADRENAL myelolipoma, an uncommon benign tumor containing hematopoietic and adipose tissue, has been found in 0.08-0.2% of autopsies¹ and in a smaller percentage of surgical biopsy specimens.²⁻⁴ Four cases have been reported in the setting of endogenous Cushing's syndrome.⁴⁻⁷ The cause of elevated glucocorticoids in these reported cases was pituitary adenoma, adrenal adenoma, or idiopathic adrenal hyperplasia. We report a case in which adrenal myelolipoma was found in association with bilateral adrenal hyperplasia due to an ectopic source of ACTH.

Case Report

The patient, a 66-year old white male, was admitted to Danbury Hospital on 5 May 1988 with a one-week history of dyspnea and nonproductive cough. His symptoms included a progressive weakness, anorexia, and a one to two pound weight loss. His past medical history included long-standing hypertension, and his current medication was spironolactone 100mg four times daily. He had a 25 year history of cigar smoking. During a recent outpatient evaluation for worsening hypertension, a chest film (29 March 1988) was normal. Two weeks prior to admission, his serum potassium level was found to be 1.8 mEq/l, associated with a decreased serum renin level (0.5 ng/ml/h). An abdominal computerized tomographic (CT) scan at that time showed a well circumscribed 5 cm mass arising from the left adrenal gland (Figure 1).

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Physical examination on admission showed a blood pressure of 170/80 and pulse of 110 supine. There were diminished breath sounds and rales at the left lung base and marked pitting ankle edema. No abdominal mass was palpated. A chest film showed a dense left lower-lobe infiltrate, patchy nodular right lung infiltrates, and a layering left pleural effusion.

His leukocyte count was 21,500/ μ l, with a left shift. The hemoglobin level was 16.2 g/dL; hematocrit 49.0%; and platelet count 99,000. The serum sodium was 139 mEq/l; potassium 2.1 mEq/l; chloride 91 mEq/l; bicarbonate 39 mEq/l, blood urea nitrogen 29 mg/dl; creatinine 1.2 mg/dl; and glucose 155 mg/dl. An arterial blood gas on room air showed pH 7.59, pCO₂ 38 mmHg, and pO₂ 33 mmHg.

On admission, intravenous fluids and antibiotics were administered and on the following day, open lung biopsies of the right upper and lower lobes were obtained. Postoperatively the patient remained hypoxemic and ventilator-dependent and developed a low-grade fever. An afternoon cortisol drawn on admission was reported to be 139 μ g/dl and a morning cortisol was 116 μ g/dl (reference range 5-20 μ g/dl). On the second postoperative day the biopsy results were reported as showing cytomegalovirus pneumonitis, invasive aspergillosis, and *Pneumocystis carinii* pneumonitis without evidence of tumor.⁹ Amphotericin B was given but despite aggressive management, the patient developed septic shock with Disseminated Intravascular Coagulation (D.I.C.) and expired on the sixth hospital day. An elevated ACTH level of 430 pg/ml, (reference range 0-70 pg/ml), drawn two weeks prior to admission, was returned postmortem. Antibody to HIV was undetectable in the serum. Multiple blood cultures remained negative.

Methods

Tissue was fixed in 10% buffered formaldehyde, embedded in paraffin, and stained with hematoxylin-eosin. Selected sections were also stained with silver-methenamine. Immunohistochemical studies were performed on selected deparaffinized sections using the avidin-biotin complex method.⁹ Primary antisera against ACTH (BioGenex, Dublin, CA) was used. Antigenically

well characterized tissues served as the positive control. The primary antibody was deleted for the negative controls.

Cortisol was measured in frozen EDTA-treated plasma by radioimmunoassay. ACTH was measured by radioimmunoassay in fasting plasma, immediately frozen after collection and assayed within 30 days of collection.

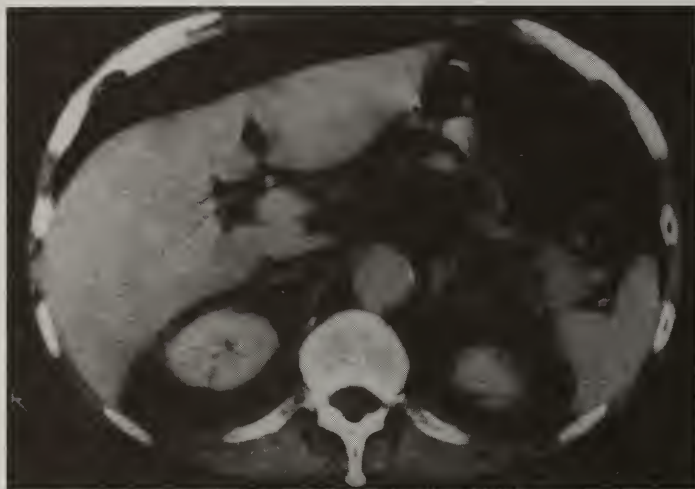


Figure 1

Computed tomographic scan of the patient showing a well-circumscribed mixed-density mass arising from the left adrenal gland.

Pathologic Findings

At autopsy, a 5.5 cm firm, tan-gray infiltrating tumor was discovered in the region of the left lower lobe bronchus (Figure 2, left). Microscopically, the tumor proved

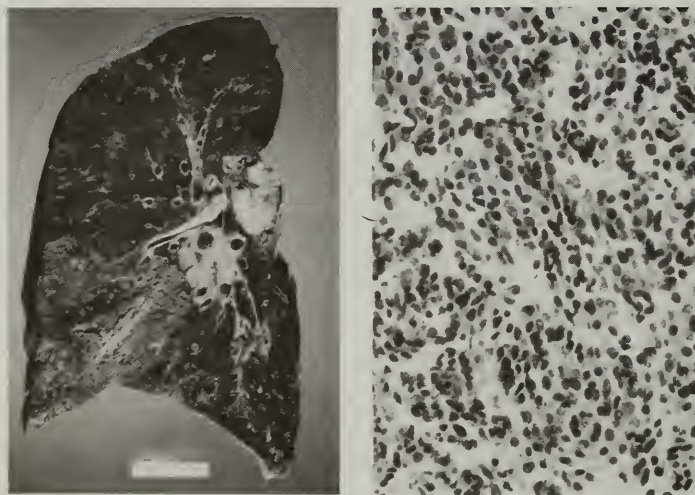


Figure 2

Left: Coronal section of the left lung showing an infiltrating tumor arising in the region of the left lower lobe bronchus and also involving the neighboring peribronchial lymph nodes. In the adjacent lung parenchyma, several *Aspergillus* abscesses are visible. Right: Section of the left lung tumor showing oat-cell carcinoma (hematoxylin-eosin, X40).

to be the oat-cell subtype of small-cell carcinoma (Figure 2, right). Metastatic tumor was present in hilar and mediastinal lymph nodes and within the liver. Sections of the tumor failed to stain for immunoreactive ACTH.

Grossly, both lungs also showed multiple cystic and miliary lesions. Microscopically, these areas showed acute inflammation, necrosis, abundant *Aspergillus* species,

Pneumocystis carinii, and changes consistent with cytomegalovirus infection.⁸ *Aspergillus* microabscesses were seen in the brain, heart, thyroid, pancreas, and kidneys.

The pituitary gland showed no significant histopathological changes. Stains for ACTH showed minimal focal positivity. This was in contrast to control tissue from pituitaries of non-Cushingoid patients and from one individual with corticotropin releasing factor-producing tumor, which were strongly positive by this method.

The adrenal glands showed bilateral cortical hyperplasia with a hypertrophic compact cell histology. A large spherical tan-brown mass measuring 5.5 cm in diameter was attached to the lateral limb of the hyperplastic left adrenal gland (Figure 3). Sections of this mass



Figure 3

Sagittal section of left adrenal gland showing a well-circumscribed mass arising from the lateral limb. The uninvolved adrenal cortex appears hyperplastic.

showed a benign proliferation of adipocytes and hematopoietic elements diagnostic of myelolipoma (Figure 4). These elements were admixed with cords of hypertrophic

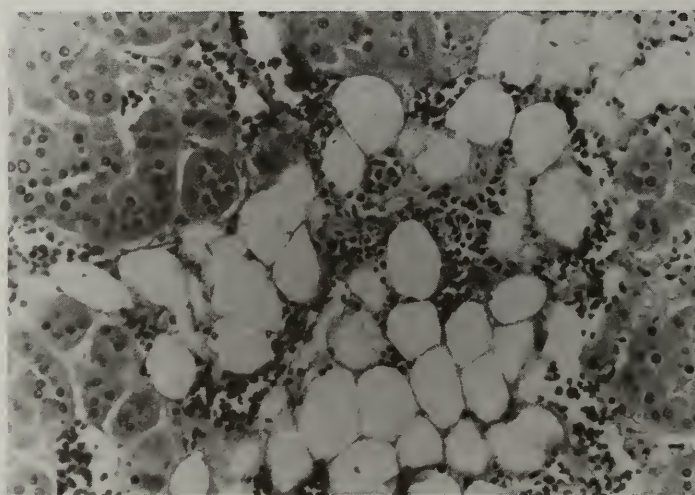


Figure 4

Section of the left adrenal mass showing a benign proliferation of adipocytes and hematopoietic elements, admixed with nests of hypertrophic compact adrenal cortical cells (hematoxylin-eosin, X20).

adrenocortical cells. The tumor failed to stain for immunoreactive ACTH.

Comment

The marked elevation of plasma ACTH (430 ug/l) in our patient in conjunction with the bilateral adrenal hyperplasia and decreased pituitary staining for ACTH point to an ectopic source of ACTH. The lipid-depleted, uniformly hypertrophied, and hyperplastic compact cell histology of both adrenal cortices is virtually pathognomonic of ectopic ACTH syndrome.^{10,11} Also consistent with this entity is the patient's presentation with hypokalemic metabolic alkalosis in the absence of the classic signs of Cushing's syndrome.

The oat-cell carcinoma of the lung is the probable ectopic source of ACTH in our patient. This tumor is responsible for about 60% of cases of ectopic ACTH syndrome.¹²⁻¹⁶ The absence of other potential sources of ACTH in our patient, including islet-cell tumor of the pancreas, thymoma, carcinoid, and medullary carcinoma of the thyroid as well as the absence of ACTH in the myelolipoma also makes an oat-cell source more likely.

The oat-cell tumor repeatedly failed to stain for ACTH by immunohistochemical techniques. This finding is not unexpected. Coates, et al, recently studied 18 cases of Cushing's syndrome caused by an ectopic source of ACTH.¹⁸ The cases were divided into two groups: one group of 12 with less aggressive or benign tumors, and a group of six with highly malignant tumors. Of the first group of 12 neoplasms, ten stained positively for ACTH, pro-opiomelanocortin (POMC), or both by immunocytochemistry. Conversely, none of the six highly malignant tumors, including three small-cell lung carcinomas (plasma ACTH 389-1502 mg/l), stained positively for ACTH or POMC. The authors concluded that a feature of these highly malignant sources of ACTH is high and rapid secretion of peptide hormones, resulting in amounts that are too small to be shown by conventional immunohistochemical techniques. The highly malignant tumor in our patient was probably behaving in such a manner.

Coexisting adrenal myelolipoma and ectopic ACTH syndrome have not been previously reported. The pathogenesis of adrenal myelolipoma in our case is not clear. Although extreme elevation of the serum cortisol is clearly documented, the nature of the ectopic source of ACTH, ie, a small highly malignant oat-cell carcinoma, is not consistent with the large size of the myelolipoma. The oat-cell carcinoma probably developed over the course of six months or less. A chest film taken six weeks prior to admission was read as unchanged from normal films taken in recent years. The 5.5cm benign myelolipoma almost certainly had been present for longer than six months, before the presence of the elevated ACTH and resulting hypercortisolism. Therefore, it is difficult to implicate a hypercortisol state as a causative factor in this case of adrenal myelolipoma. The simultaneous occurrence of ectopic ACTH and adrenal myelolipoma in this patient is probably coincidental.

Myelolipoma is a benign adrenal neoplasm consisting

of lipid and hematopoietic elements in varying proportions. This entity is uncommon, usually found as an incidental finding at autopsy. Less than 200 cases have been reported in the literature. It is widely held that the origin of both lipid and myeloid cells within the myelolipoma is the precursor reticulum cell.¹⁸ The nature of the stimulus required to cause this differentiation is not understood.

Adrenal myelolipomas have often been found in patients with chronic and stressful conditions, such as major burns¹⁹ and malignancy.³ These clinical states are associated with excess cortisol production as an adaptation to stress. Selye and Stone were able to produce adrenal myelolipomas in rats by injection of crude ACTH-containing anterior pituitary extracts and testosterone.²⁰ These observations suggest that stimulation with ACTH or cortisol may be involved in the pathogenesis of adrenal myelolipoma.

In the past decade, four cases of adrenal myelolipoma occurring in association with Cushing's syndrome have been reported. Causes of hypercortisolism in these patients were pituitary adenoma,^{4,7} adrenal adenoma,⁶ and autonomous bilateral adrenal hyperplasia.⁵ The authors postulate a role for glucocorticoids in the pathogenesis of adrenal myelolipoma.

Of interest is the radiologic appearance of the left adrenal myelolipoma by CT scan (Fig 1). Although radiologic signs are often equivocal, myelolipomas generally have fat density values on CT scans and appear well circumscribed.⁵ Our case satisfied these criteria. Also of interest is the failure of the CT scan to detect the bilateral adrenal hyperplasia in this case. Adrenal hyperplasia is difficult to detect with CT because the degree of cortical thickening is often only a few millimeters above normal. However, when marked bilateral adrenal enlargement is demonstrated by CT, the most likely cause is an ectopic ACTH-producing neoplasm, regardless of the results of high dose dexamethasone suppression.²²

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50 Years Ago

From the *Journal of the Connecticut State Medical Society* January 1939

THE SYPHILIS CAMPAIGN

"Behind the Syphilis Campaign," a pamphlet compiled by Dr. Philip S. Broughton with the aid of members of the Division of Venereal Diseases of the United States Public Health Service, has just been issued by the Public Affairs Committee of New York City. It carries a message to the lay public about syphilis and within its covers the author briefly describes the symptoms of syphilis and the methods of spread.

Each year 518,000¹ cases of newly infected patients report to doctors and clinics for treatment and, in addition, 598,000 advanced cases come to doctors for the first time. The advanced cases are important because they had a year or more during which they were uncontrolled and able to spread the disease. Nearly half of these infections are innocently acquired: in marriage, at birth, through chance contacts, or, rarely, through soiled towels, drinking cups and similar articles. The author points out that were the syphilis rate in the United States as low as it is in Denmark, we would have 26,000 cases instead of more than 1,000,000.

The cost of this disease is stupendous and is summed up in a slogan of the United States Public Health Service: "The cheapest thing America can do with its million cases of syphilis is to cure them."

The modern approach in the current campaign to eradicate syphilis has, as its keynote, the appeal to confidence and not to fear, because a frightened patient is likely to take the wrong course and a quack may quiet his fears more quickly than an honest physician. Specifically, the present campaign directs itself to the creation of adequate facilities for diagnosis and treatment, routine blood tests and the follow-up of cases.

The author stresses the fact that syphilis can be cured and that early treatment shows the best results. Even in late stages, however, treatment markedly diminishes the frequency of brain and nervous system involvement. In an untreated syphilitic mother there are five chances out of six that the baby will be born dead or infected with syphilis, whereas, in the cases of the treated mother, the baby will be healthy ten times out of eleven.

The United States Public Health Service has formulated a policy for industry in its relation to syphilis. In brief this policy encourages the following: (1) Routine blood tests for job seekers with employment if syphilitic, providing treatment is accepted. (2) Blood tests as part of regular physical examination of employees. (3) Educational program which will give employees an understanding of the problem. (4) Treatment of employees by industrial medical services, unless competent treatment can be arranged through private physicians.

— Editorial by Creighton Barker, M.D.

1. Compared with about 40,000 in 1988 (from *MMWR*, 16 December 1988.-Editor). See also this issue, pp. 35-6.

Adenocarcinoma of the Cervix Arising in Pregnancy

MARIA P. LENAZ, M.S., M.D. AND RICHARD Z. BELCH, M.D., PH.D.

A CASE of invasive adenocarcinoma of the cervix in pregnancy is reported. A review of the literature reveals that this neoplasm is infrequently encountered during pregnancy. Cervical carcinoma is the most frequently occurring malignancy in pregnancy. The frequency of diagnosis of cervical carcinoma during pregnancy is increasing as initial prenatal obstetric management involves routine Papanicolaou smears. A brief review of the literature will be presented.

Introduction

Cervical carcinoma is the most frequently occurring malignancy in pregnancy, followed by breast carcinoma.¹ The literature states that primary adenocarcinoma of the cervix comprises approximately 10% to 15% of all new cases.² However, reports of cervical adenocarcinoma associated with pregnancy are rarely encountered. Primary adenocarcinoma of the cervix and endocervix is cytologically evasive, variable in its histologic appearance, and confusing from a therapeutic standpoint.

There is a delay in the early diagnosis of adenocarcinoma of the cervix. Cervical cytology has not been as helpful in the early detection of adenocarcinoma of the cervix as it has been for squamous cell carcinoma.^{2,3}

The histologic diversity of this lesion may be responsible for the more advanced stage at the time of the diagnosis. This is one of the factors that has been associated with a poorer prognosis for this neoplasm when compared to squamous cell carcinomas.^{2,3} Other factors affecting prognosis are related to lower uterine segment involvement, local growth, and the frequency of distant metastases.

The possibility of a hormonally mediated etiology of adenocarcinoma of the cervix has been suggested.

Peters et al hypothesize an association between cervical adenocarcinoma and oral contraceptive use in early adolescence, but state that further studies are needed to verify this relationship.⁴

Hacker et al reviewed 579,795 pregnancies for invasive

disease and found an incidence of one in 2,205. The majority presented with abnormal bleeding, whereas a smaller percentage were asymptomatic. Most patients present with a gross lesion, requiring a biopsy for diagnosis. There is a reported 8% to 40% false negative rate when random biopsies are used.^{6,7}

Invasive carcinoma of the cervix in pregnancy is associated with an average age of 33 years. This age is significantly lower than the average age reported for nonpregnant women with invasive cervical carcinoma. The majority of patients were grand multiparas.^{8,9,10}

Case Report

M.H. was a 29-year-old female, married, gravida 1 para 0, with an uncomplicated pregnancy until 37 weeks' gestation when a polypoid mass was discovered on the anterior lip of her cervix. A punch biopsy measuring approximately 1.5 cm x 1.0 cm x 0.3 cm was obtained. The histologic study revealed only a blood clot containing acute inflammatory, squamous, and glandular cells.

The patient had been otherwise in good general health. She had begun to menstruate at 13 years, with regular cycles every 28 days, lasting 3 to 4 days. She had annual gynecological examinations with normal Papanicolaou smears. Her last smear, at her initial prenatal visit, was Class I. She had a ten-year history of oral contraceptive use without any difficulties. She denied using estrogen, or in utero diethylstilbesterol exposure. Her past medical history and surgical history were unremarkable. She has a known sensitivity to penicillin. She admitted to smoking one-half pack of cigarettes daily for two years, but had stopped one year before this pregnancy. She had a negative family history for carcinoma.

She had an episode of vaginal spotting after a pelvic examination at 38 weeks, which resolved spontaneously. She had a reactive nonstress test, and no further bleeding episodes. An earlier ultrasound examination had revealed an anterior right lateral and fundal placenta; a single intrauterine pregnancy, in a vertex presentation, with a confirmed age of gestation, normal fluid volume, fetal movement, and other parameters observed, and no evidence of placenta praevia.

The patient was admitted in active labor with intact membranes at 41 weeks age of gestation. She underwent a primary cesarean section for fetal distress, at which

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time a polyp was excised from the right lower cervical segment and sent for pathological examination. She was delivered of a living male infant, weighing 7 lb. 12 oz, with Apgar scores of 9¹/10⁵, from a left occiput posterior position. A nuchal cord x 2 was noted, as well as meconium-tinged fluid.

She was empirically given gentamicin intravenously for prophylaxis. Her postoperative course was notable for an endomyometritis for which intravenous clindamycin was added to the gentamicin therapy. After being afebrile during 48 hours of intravenous therapy she began oral therapy, and was discharged home on her sixth postoperative day.

Pathological studies revealed an invasive moderately well-differentiated adenocarcinoma of the cervix. Occasional solid components, mucin production, acute inflammation, and lymphatic vessel invasion were observed. The placenta was normal.

She was referred for treatment of a stage IB adenocarcinoma of the cervix.

The preoperative laboratory work was within normal limits, as was an intravenous pyelogram.

She underwent a cystoscopy, proctoscopy, and an examination under anesthesia.

Cystoscopic and proctoscopic examinations were entirely normal. A bimanual and rectovaginal examination revealed no abnormalities. The uterosacral ligaments and parametria were not thickened or irregular.

A radical hysterectomy, bilateral salpingectomy, and paraortic, common iliac, and pelvic lymphadenectomy were performed. At operation there was no evidence of gross adenopathy; the frozen section was negative for tumor; examination of the uterus revealed tumor in the endocervix.

The final pathologic diagnosis was consistent with reactive serosal and peritoneal inflammation in the parametrium and peritoneal cavity, with no evidence of malignancy. The pelvic lymph nodes, paraortic, obturator, and hypogastric nodes showed no tumor.

Her postoperative course was notable only for paresthesias of the digits of her left hand. A neurologist felt that the paresthesias were the result of irritation by the radial arterial line; they resolved without any residual deficit. She was discharged on the seventh postoperative day in good condition, and has required no further treatment.

Discussion

Although the coincidence of cervical adenocarcinoma and pregnancy is known,^{2,8,11} this case illustrates an unusual presentation and coexistence of this invasive adenocarcinoma of the cervix and pregnancy.

As glandular involvement tends to be focal, a biopsy specimen may prove to be unsatisfactory when only surface involvement is sampled.¹² The fact that adenocarcinoma can metastasize as whole glands may cause difficulty in differentiating between adjacent intraepithelial changes and invasive disease.

In view of the nature of the lesion and the site, it is

understandable that routine cytological smears may not necessarily include cells revealing a malignancy.^{13,14}

It is known that cervical tissues are responsive to estrogens, and it appears that cervical adenocarcinoma is more responsive than its squamous counterpart.^{4,15} It has been proposed that the use of oral contraceptive pills may be linked to cervical cancer or its precursors.^{4,16}

The treatment for invasive disease, radical hysterectomy versus radiation therapy, is based on the stage of the cancer and is the same as that used in the nonpregnant state. The survival rate seems to be unchanged from that of the nonpregnant patient.^{7,9,17} In a report of 49 cases of stage IB cervical carcinoma in pregnancy by Niskier and Shubat,¹⁸ the five-year survival rates and complications are compared for both modes of therapy. According to their data, the radical hysterectomy and pelvic lymphadenectomy, with subsequent radiotherapy for tumor positive nodes, appears to be the preferred form of treatment when the diagnosis is established in mid- or late trimester of pregnancy.¹⁸

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Important Advances in Clinical Medicine

Pediatrics

The Scientific Board of the California Medical Association presents the following inventory of items of progress in pediatrics. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers, or scholars to stay abreast of these items of progress in pediatrics that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Pediatrics of the California Medical Association and the summaries were prepared under its direction.

Ribavirin and Respiratory Syncytial Virus Infections

RESPIRATORY Syncytial Virus (RSV) is the most frequent cause of hospital admissions of infants with respiratory tract disease. In previously healthy infants, the RSV infection subsides in three to seven days, and most infants recover without sequelae; some will have reactive airway disease with subsequent respiratory tract infections. Substantial morbidity and, infrequently, death may occur among infants with preexisting severe pulmonary or cardiac disease. Most severely affected infants have signs and symptoms of bronchiolitis or acute pneumonitis, or both, and clinically significant hypoxemia develops due to bronchiolar spasm or alveolar-capillary block, or both. A significant proportion of the sickest infants require ventilatory support. In those infants with severe bronchopulmonary dysplasia, severe cyanotic heart disease with increased pulmonary blood flow, and cellular immunodeficiency syndromes, the outcome may be uncertain.

RSV infection is generally limited to the respiratory tract epithelium; the pathogenesis of the disease probably is an extensive cellular pathologic disorder and acute host-mediated responses, including immunoglobulin (Ig) E-mediated activity. Ribavirin aerosol therapy, developed over the past decade, appears to ameliorate or diminish these pathologic events.

Ribavirin (Virazole) is a nucleoside analogue that is activated in host tissues to its phosphorylated form; anti-

viral activity results in the inhibition of viral RNA synthesis. Ribavirin aerosol therapy was pioneered in controlled studies among college students with acute influenza virus A infections and then extended to RSV infections among infants. Therapeutic efficacy has been shown among infants and children admitted to hospital with and without preexisting pulmonary and cardiac disease. Benefits occur without significant drug toxicity, and five-year follow-up evaluations show no effects of the aerosol therapy on the respiratory tract.

High concentrations of ribavirin are delivered in an aerosol by a small-particle aerosol generator through a mask, tent, or endotracheal tube over a 12- to 18-hour treatment period per day for three to five days or, in some cases, longer. The respiratory staff needs to give careful attention to drug precipitation in the respiratory equipment during therapy, especially among patients with endotracheal tubes in place.

In general, ribavirin therapy may be expected to control chronic infections among immunocompromised patients and to ameliorate infections among other treated inpatients. The most significant result of therapy is the relief of hypoxemia; this may be due to the control of the virus infection, an inhibition of IgE-mediated responses by ribavirin, or both. Ribavirin aerosol therapy may be indicated in infants and young children with RSV infection complicated by pneumonia, apnea, progressive bronchiolitis with hypoxemia, congenital heart disease, and chronic lung disease.

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Update on α -Fetoprotein Screening

Screening of all pregnancies for neural tube and other birth defects, using the maternal serum α -fetoprotein (AFP) level, is now a routine practice.

AFP produced by the fetal liver appears in the maternal serum in a measurable quantity by the 15th completed week and increases in concentration until term. Maternal serum AFP results are reported as multiples of the median value for a given gestational age and, as such, have provided a number of insights into conditions affecting a fetus or pregnancy.

The usefulness of maternal serum AFP screening is improved with accurate pregnancy dating when raw values are adjusted for race, body weight, and the presence of insulin-dependent diabetes. The AFP levels can be raised or lowered in maternal serum by several conditions affecting fetal production or transplacental or amniotic diffusion. These conditions include multiple gestations; fetal demise; and structural fetal defects such as open spina bifida, gastroschisis, and omphalocele. It is necessary, therefore, to examine carefully the pregnancies of women having abnormal AFP values. This begins with ultrasonography to confirm the gestational age and the presence of a single fetus that is viable and has no structural defect. A woman with an abnormal elevation unexplained by ultrasonography should have a specimen of amniotic fluid collected for karyotyping and AFP determination. If the AFP level is elevated, the acetylcholinesterase, an enzyme specific for neural tissue, is assayed. An elevation supports a diagnosis of open spina bifida.

The test should be done at a university or a referral laboratory with a large enough volume and experience to guarantee an accurate analysis and interpretation. The test is available in most states. California has pioneered and administered a statewide program that has screened more than 500,000 women. This program has proved to be cost-effective. The cost of care saved by termination or early treatment is about twice the cost of detection. Following this protocol, approximately 95% of anencephalic fetuses, 80% of those with open spina bifida, and many fetuses with ventral wall defects could be detected prenatally.

For several years women older than 35 years at term have been offered an amniocentesis for the prenatal detection of Down's syndrome. Because fetuses with the

Down syndrome usually produce less AFP, low maternal serum AFP levels can now be used in women younger than 35 to identify an additional group of trisomic fetuses. The combination of maternal age and serum AFP levels in multiples of the median can be used to assign specific risk figures. Women with a risk equivalent to 35 years should be offered an amniocentesis. About 15% to 20% of cases of Down's syndrome are detectable by this method.

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Varicella Vaccine Update

The first report of varicella vaccine appeared in *The Lancet* a decade and a half ago. Since that time the vaccine has been licensed for use in Japan and in Europe. In the United States, the vaccine has been evaluated in thousands of normal children and in hundreds of normal adults and children with leukemia. Why has the vaccine not been licensed in this country? Varicella vaccine has been shown to confer good protection in healthy children and to modify or prevent disease in adults and in children with leukemia. In the latter groups, its use certainly reduces the morbidity that varicella is known to produce in these persons. In children with leukemia, there have been some reactions to the vaccine that are difficult to predict. In healthy children the vaccine is safe.

The main concern appears to be about the long-term effects of immunization: whether the vaccine will result in more or less zoster than in patients with natural infection. Studies in children with leukemia, however, do not suggest that there is increased risk, and, indeed, zoster may be less frequent in vaccinees. Another concern is whether the widespread use of the vaccine will result in a greater frequency of adult cases of varicella. This might occur if vaccine-induced immunity wanes or if the epidemiology of varicella is changed by reducing the opportunities for natural infection in those children who are not immunized. By combining the varicella vaccine with a vaccine that is given to virtually all children, such as the measles, mumps, and rubella vaccine, the latter concern can be assuaged. This combination has been shown to be safe and effective.

It is unlikely that we will have additional answers to these possible problems by more testing. A decision on licensure is probably at hand.

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Pediatric Physical Assessment of Sexual Abuse

Child sexual abuse has been increasingly recognized in recent years. While physicians are sensitive to the psychological and social aspects of the medical evaluation, they need to be aware of the medical findings on physical examination associated with genital trauma and to understand the significance of sexually transmitted diseases in prepubescent children.

There is normal variation in the anatomy of the anogenital area of prepubescent children. Not all changes in the genital area are due to sexual abuse.

In general, the genital area of a prepubescent girl contains thin, fine structures that are scarred as a result of certain types of injuries. Not all forms of sexual abuse result in observable findings. Oral-genital contact and gentle fondling, for example, may result in no changes. External rubbing, also called vulvar coitus or dry intercourse, characteristically results in changes in the area of the posterior fourchette and occasionally hyperpigmentation of the labia majora. Actual penetration with either finger, penis, or foreign object will usually lead to disruptions in the configuration of the hymen. With a single isolated episode, the initial signs of trauma may heal within one to two weeks, and there may be minimal residual findings. With repeated episodes, the traumatized area may not have sufficient opportunity to heal, and greater changes are noted. In summary, the changes noted with repeated vaginal penetration are a reduced hymenal remnant; irregularities in the hymenal contour representing healed tears; rounding and thickening of the hymen; missing portions of the hymen; and a gaping patulous introitus. There has been controversy concerning the size of the hymenal orifice as an indication of sexual abuse. In general, the orifice is 3 to 4mm in girls younger than 5 years and up to 5 to 6mm in girls between 5 and 10 years old. There is no consensus about these measurements, however, and the finding of an enlarged orifice without other changes may not be diagnostic of abuse.

Repeated penetration of the anus may lead to physical findings in only 50% of the victims. Scarring, thickening, and hyperpigmentation of the perianal skin; a diminution in the number of rugae; a loss of tone; and a loss of subcutaneous supporting tissue may be present.

The presence of a sexually transmitted disease also supports the diagnosis of sexual abuse. These diseases

include gonorrhea, *Chlamydia*, *Trichomonas*, syphilis, condylomata acuminata, and herpes simplex type 2. The presence of any of these diseases warrants further medical and psycho-social evaluation.

Referral centers with expertise in pediatric sexual abuse may assist a clinician through experienced interviewers and with the aid of colposcopy, which provides magnification for a visual examination of the injured genital tissue.

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Jaundice in Healthy Newborns—Redefining Physiologic Jaundice

Because clinical jaundice becomes apparent at serum bilirubin levels of about 5mg per dl, about 65% of all normal newborn infants appear jaundiced during the first week of life. Although the overwhelming majority of these infants are healthy, the presence of jaundice engenders anxiety in parents and physicians alike, and the management of what in most cases is a "nondisease" is emotionally and financially draining. Most pediatricians follow the advice of standard pediatric texts and do diagnostic investigations to rule out "pathologic" jaundice whenever the bilirubin level exceeds 12 to 12.9mg per dl.

We studied 2,416 infants admitted consecutively to a well-baby nursery and found that the maximal serum bilirubin concentration exceeded 21.9mg per dl in 147 infants (6.1%). Jaundice was associated strongly with breastfeeding ($P = .0001$) and the percentage of weight loss after birth ($P = .0001$) as well as maternal diabetes, Asian race, decreased gestational age, male sex, bruising, and the induction of labor with oxytocin. Using logistic regression analysis, we calculated the risk of jaundice for infants with or without these "icterogenic" factors. These calculations permit pediatricians to predict the likelihood of jaundice developing in a particular infant. When many risk factors are present, there is a high probability of jaundice, and, provided the baby is otherwise healthy, it is probably unnecessary, almost always unrewarding, and certainly expensive to do a battery of laboratory tests. On the other hand, we should be wary of a modestly elevated serum bilirubin level in an infant with jaundice who has few or no icterogenic risk factors. This might require further investigation.

Based on the method of feeding alone, the 95th percentile for the maximal serum bilirubin concentration in breast-fed infants is 14.5mg per dl, whereas it is only 11.4mg per dl for bottle-fed infants. All other factors

being equal, therefore, it should not be necessary to investigate a case of a jaundiced, healthy, breast-fed infant unless the serum bilirubin level exceeds about 15mg per dl, whereas in a bottle-fed infant such investigations may be indicated if the serum bilirubin level exceeds about 12mg per dl. Including the other risk factors mentioned above further refines this approach. We need a new definition of what is, and what is not, physiologic jaundice.

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AIDS in Schools and Day-Care Centers

American children younger than 13 years diagnosed with the acquired immunodeficiency syndrome (AIDS) numbered 934 by April 1988. The estimated number of cases in 1991 is 3,000. Many children with AIDS are well enough to benefit from the developmental and educational opportunities of day-care attendance and elementary school education. In addition to the number of children with AIDS are children with the AIDS-related complex and those without symptoms but who are seropositive for antibodies to the human immunodeficiency virus (HIV). Children acquiring HIV in the perinatal period are asymptomatic for an average of six to eight months. Those who acquired the infection before 1985 from a transfusion of blood or blood products have had a mean incubation period of two years. Some have remained asymptomatic for as long as seven years.

The enrollment of these children in child-care settings and elementary schools has raised concern among those providing these services. Child-care and school issues requiring physicians' responses include the communicability of HIV to healthy children and staff, mandatory serologic screening, the potential for secondary infections in children with AIDS, and conflicting obligations to protect privacy and to inform.

Responses to such concerns are based on the current understanding of HIV communicability. The nonsexual household transmission of HIV is rare; the few reported cases involve extraordinary circumstances and poor adherence to hygienic precautions. Not one case of HIV infection has been transmitted in a school or day-care setting. Although HIV has been identified in saliva, tears, and urine, there is no evidence that these fluids are involved in the transmission of the infection.

Casual contact as would occur among children in an elementary school should not be considered a risk for the communicability of HIV. The benefits of unrestricted

school attendance to most school-aged children seropositive for HIV outweigh any remote risk of viral transmission. HIV-seropositive infants, toddlers, and older children with subnormal development are more likely to lack control of their body secretions and to practice frequent hand- and object-mouthing behaviors and biting behaviors. These children and HIV-seropositive children with oozing skin lesions hypothetically pose an increased risk to others. For these cases, exclusion from a group program should be decided on a case-by-case basis by qualified persons including the child's physician and a person familiar with the educational setting.

Hygienic practices in day-care centers and schools can contain the spread of infectious diseases and are recommended in the presence or absence of known HIV-infected persons. Child-care personnel and educators can minimize their exposure to HIV by carefully attending to hand washing. In regions with a high prevalence of HIV infection, consideration should be given to protecting open skin lesions and dry, cracked skin with disposable gloves when handling body fluids and excrement. Caution in disposing of soiled towels, diapers, and sanitary napkins must become routine. Soiled surfaces and mops should be cleaned with disinfectants (household bleach diluted 1:10 with water).

Mandatory screening for HIV as a condition for school or day-care enrollment is unwarranted. A physician, not the educational facility, should be responsible for assessing the risk of secondary infection to an HIV-positive child who may be immunosuppressed. Notifying school personnel of a child's HIV status would expedite preventive action by the parent or physician of an immunocompromised HIV-positive student when there is a school epidemic. The cost of even limited disclosure, however, will often be the needless ostracism of the child from school. Information about a child's immunodeficiency, regardless of its cause, should be disclosed to certain care givers, but a child's HIV-seropositive status is to remain confidential information. Exceptions may be to inform those staff members who directly care for children with frequent biting behavior or children incapable of controlling body secretions.

The responsibility of the schools goes beyond safely enrolling HIV-seropositive children in their classrooms. Given that vaccine development is not imminent, community education is the most efficient means of controlling the spread of HIV, and schools have the capability and responsibility to provide this education. Guidelines for an educational curriculum directed towards various grade levels are available from the Centers for Disease Control to educators who want an effective strategy to teach students how to avoid HIV infection.

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Management and Ethical Dilemmas of Diagnosing and Treating Fetal Heart Disease

Major advances in ultrasound imaging over the past ten years currently provide a systematic approach to evaluating the anatomy, physiology, and rhythm of the fetal heart, with detailed imaging available as early as the 14th to the 15th week of pregnancy. Pediatric cardiologists, perinatologists, and radiologists, often working together, have diagnosed almost every major form of congenital heart disease correctly before birth. Such notable success has not come easily, and, in general, physicians working in this area have often required two to five years of extensive experience to achieve proficiency using ultrasound for a detailed cardiovascular evaluation before birth.

Indications for fetal cardiac ultrasonography include maternal diabetes, maternal drug exposure, maternal infection, a family history of congenital heart disease in a parent or sibling, or persistent fetal arrhythmia. The largest "pick-up" rate for major forms of congenital heart disease will occur if obstetricians evaluate a four-chamber cardiac view as a part of their routine obstetric ultrasonographic screening procedure. They should see the atrial and ventricular septa and four chambers relatively symmetrically dividing the cardiac ultrasound "silhouette" in this plane. Perhaps 90% of the major forms of congenital heart disease can be ruled out by a normal four-chamber view.

Alternatives available in the aftermath of the diagnosis of congenital heart abnormality may include pharmacologic therapy for an arrhythmia; counseling a family about the natural history—catheterization, heart operations, and the like—of infants with similar forms of congenital heart disease after birth; and counseling related to terminating a pregnancy in the appropriate circumstance or making arrangements for the timing and method of delivery for the appropriate medical or surgical intervention after birth, including consideration of a neonatal heart transplantation for certain inoperable conditions. Major additional capabilities for evaluating the fetal heart have arisen with the application of the Doppler to evaluate cardiac function in cases of valvular disease, and high-resolution color flow mapping has assisted in evaluating septal defects as well as the aortic

arch and conal truncal abnormalities.

The field of fetal cardiology is rapidly advancing. It requires the highest level of technical skills and cooperation among obstetric, pediatric, neonatal, ethical, legal, genetic, and surgical colleagues. Several tertiary hospitals have developed centers for fetal diagnosis and treatment where such multidisciplinary expertise can be coordinated, not only for cardiac but for other organ system diseases diagnosed and potentially treated in the fetal stage. Through regionalized team efforts, advances in this dynamic area of fetal medicine will be controlled and yet nurtured to encourage further advances.

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Exogenous Surfactant for the Respiratory Distress Syndrome

Since the 1970s, therapy for the neonatal respiratory distress syndrome has focused on metabolic resuscitation and assisted ventilation of preterm infants with ventilatory failure until the gene controlling surfactant production and secretion is activated. Surfactant deficiency is central to the pathophysiology of the respiratory distress syndrome. Successful exogenous surfactant administration has led to the development of several promising surfactants for exogenous use.

Human surfactant, derived from amniotic fluid, contains all surfactant proteins (SP-A, -B, and -C), phospholipids identical to "mature" adult surfactant, and a small percentage of neutral lipids. Human surfactant instilled into the airways has been shown to reverse ventilatory failure from the respiratory distress syndrome; to bring about a rapid improvement in oxygenation; and, in very premature infants, to decrease the mortality and the prevalence of bronchopulmonary dysplasia.

Several "first-generation" surfactants have shown promise in clinical trials. Surfactant TA, calf lung surfactant extract, and human surfactant are currently being evaluated in multidose clinical trials to establish efficacy and safety. Synthetic surfactant, not derived from natu-

ral sources and void of surfactant protein (Exosurf), is concurrently being studied in similar trials. Both preventive treatment and postventilatory "Rescue" trials of surfactant treatments are being systematically investigated using these surfactants. Using human surfactant has thus far been free of complications, and the two-year neurodevelopment follow-up evaluation suggests an overall improvement in treated infants.

Critical advances in isolating surfactant components and cloning suggest that recombinant surfactants, comprising critical proteins or biologically active peptides and phospholipid mixtures in ideal combinations, will become "second-generation" surfactants.

Until the efforts of genetic engineering are successful, neonatologists will be limited to using natural surfactant derivatives or artificial surfactants in carefully controlled trials sanctioned by the Food and Drug Administration. Of course, only premature infants with evidence of surfactant deficiency should receive this experimental therapy. If the present trials are successful, surfactant therapy should by 1990 become a mainstay of the treatment of the respiratory distress syndrome.

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Bronchopulmonary Dysplasia (Infantile Chronic Lung Disease)

With the increased survival of neonates who have severe respiratory insufficiency, bronchopulmonary dysplasia has become an important cause of chronic illness during the first five years of life. Causes of respiratory tract injury in early infancy that may lead to bronchopulmonary dysplasia include lung immaturity (hyaline membrane disease); aspiration syndromes; infection, especially viral; and respiratory tract malformations associated with impaired mucociliary function and chronic airways soilage. These infants survive with impaired mucociliary clearance mechanisms, increased bronchial reactivity and bronchomotor tone, and impaired lung water dynamics.

While diuretic and bronchodilator therapy continue to be mainstays of management, recent studies have shown the importance of adequate oxygenation for the recovery from bronchopulmonary dysplasia. Maintaining an arterial oxygen tension above 85 torr is desirable. Occult, sometimes life-threatening hypoxemia has recently been described in patients with bronchopulmonary dysplasia who have relatively mild clinical disease. Such infants benefit from a predischARGE evaluation of gas exchange in all activity states by continuous transcutaneous monitoring of blood gas measurements so that supplemental oxygen can be prescribed for vulnerable periods during daily activities.

Lung reinjury must be avoided. Intercurrent infections—including extrapulmonary infections—should be treated aggressively, and influenza prophylaxis and treatment should be undertaken for any infants older than 6 months. Pertussis immunization is essential even for those infants receiving anticonvulsant therapy. Gastroesophageal reflux must be treated aggressively to avoid aspiration reinjury. Environmental sources of lung injury such as pollution, side-stream cigarette smoke, and exposure to talc should be avoided.

The recovery from bronchopulmonary dysplasia is associated with normal growth and repair of the respiratory tract. Growth failure frequently occurs as a consequence of chronic hypoxemia, increased oxygen consumption, and an inadequate intake of protein and other calories compared with the increased caloric expenditure. Therefore, continuing nutritional assessment and management are important.

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Transient Erythroblastopenia of Childhood

Transient erythroblastopenia of childhood (TEC) is characterized by the gradual development of anemia—a hemoglobin level of 2 to 8 grams per dl—reticulocytopenia, and a pronounced reduction of bone marrow erythroblasts. The platelet count is normal to increased. The leukocyte count is usually normal, although 20% of children may have significant neutropenia (less than 1,000 neutrophils per μ l). The disorder occurs in previously healthy young children from 6 months to 4 years of age and is seen with equal frequency in boys and girls.

Occasionally cases of the disorder occur in clusters, suggesting it may be a consequence of some seasonal environmental toxin or virus. To date, however, serologic studies have failed to reveal exposure to a common virus. Published data suggest that anemia is due to a transient antibody-mediated suppression of normal erythropoiesis.

The natural history of TEC is that all patients recover spontaneously in a few weeks and there are no long-term hematologic sequelae. In many children with the disorder, particularly if there is evidence of recovery at the time of diagnosis, no specific therapy other than careful observation is necessary. Erythrocyte transfusions are indicated only if a child is symptomatic from the anemia. Neither iron nor steroid therapy has any role in the management of this disorder.

The diagnosis often is confused with that of iron deficiency anemia, although the erythrocytes in patients with TEC are normocytic (mean corpuscular volume [MCV], 70 to 85 fl), whereas iron deficiency anemia is characterized by microcytosis (MCV, 50 to 70 fl). Transient erythroidopenia of childhood also may be confused with Blackfan-Diamond anemia, although the latter generally presents before 6 months of age, often is associated with congenital abnormalities, and invariably is characterized by macrocytic erythrocytes (MCV, 85 to 100 fl) with many fetal-like features. Because some children with TEC also have significant neutropenia, there occasionally is confusion with the diagnosis of aplastic anemia or acute leukemia, but this is readily clarified by examining the bone marrow.

Reports recognizing TEC as a distinct disorder first appeared in 1970. The general impression among most pediatric hematologists, however, is that the incidence of this acquired erythrocytic aplasia in children is increasing. At our own institution, three cases of TEC were diagnosed from 1979 to 1982, whereas 29 children with TEC were seen from 1983 to 1987. Because the magnitude of anemia in this disorder is usually severe, it is unlikely that it previously existed as an unrecognized condition that is now being more readily recognized.

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Adolescent Suicide and Depression

Suicide is the third leading cause of death in adolescents (aged 10 to 19 years), with a 1985 rate of about 9 deaths per 100,000 in this population. Of all deaths during adolescence, 14% are a result of suicide. Rates differ greatly by age, race, and gender; white and Native American male adolescents in the 15- to 19-year-old

group have the highest rates. Since 1960, the incidence of suicide has increased by 200% in the 15- to 19-year-old age group. The frequency of nonfatal attempts and gestures is difficult to document. It is estimated that for every completed suicide, there are 50 to 200 attempted suicides, with a female preponderance in this group as compared with a male preponderance in completed suicides. Cluster suicide, the occurrence of multiple suicides in a circumscribed geographic location during a short time period has recently appeared. The media have been implicated as an etiologic agent in these suicides because of imitative behavior in the suicidal acts following newspaper stories and televised movies.

Methods used include firearms for boys and girls, with hanging and jumping as the second method for boys and girls, respectively. Drug overdosing is the most common method of attempted suicide but remains uncommon in completed suicides.

Common etiologic factors include a family history of completed or attempted suicide, a previous suicide attempt, substance abuse, aggressive or impulsive behavior, depression associated with behavior problems in male adolescents, sexual abuse, depression, manic-depressive psychosis, learning disorders, and knowing someone who committed or attempted suicide. Certain precipitating events that occur before the suicide attempt include conflict with a parent or friend that is experienced as rejection, anxiety over change, substance abuse, school problems, social isolation, hypochondriasis, pregnancy, and trouble with the law.

Depression remains the common etiologic feature in adolescent suicide, with reported incidence rates of 1.0% in boys and 1.5% in girls; yet the diagnosis in an adolescent remains difficult because the signs and symptoms are more often depressive equivalents and often are attributed to normal adolescence. Depressive equivalents include a decrement in school performance, problems with the law, hypochondriasis, substance abuse, and family conflicts. Adolescent depression has three common features: changes in mood and relationships, thinking, and bodily functioning. Genetic predisposition is increasingly a cause of depression, especially in those young people whose depression begins in childhood and adolescence.

Adolescents who are depressed or contemplating suicide are difficult to engage in treatment. Special attention should be given to those with a family history of suicide, street youth, pregnant girls, and teenagers who have problems with the law. Intervention should focus on querying all adolescents about their feelings of sadness and suicidal ideation, informing young people about mental health problems and the availability of resources, de-emphasizing the romanticization of suicide as portrayed in the media, and engaging depressed and high-risk adolescents in appropriate therapeutic environments.

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Treatment of Obesity in Adults

AMA COUNCIL ON SCIENTIFIC AFFAIRS

Concern with weight control should begin sufficiently early in life to reduce the risk of developing obesity. The complex etiology of obesity is, in part, responsible for the difficulty physicians encounter in treating this condition. Prevention is the "treatment" of choice. Early identification of individuals genetically at risk can be helpful in targeting those most likely to gain excess weight. Numerous dietary regimens have been devised in an attempt to achieve progressive weight loss in obese individuals. Since the ultimate goal of a weight-reduction program is to lose weight and maintain the loss, a nutritionally balanced, low-energy diet that is applicable to the patient's life-style is most appropriate. Increasing energy expenditure through physical activity, in addition to decreasing energy intake, generally improves results in the management of obesity. Major changes in eating and exercise behaviors are necessary to ensure long-term weight control. Diet, exercise, and behavior modification are interdependent and mutually supportive. A comprehensive weight-reduction program that incorporates all three components is more likely to lead to long-term weight control.

THIS report assesses the role of diet, physical activity, and behavior modification in the treatment of obesity in adults. It does not discuss the use of anorexiant, which is covered in *Drug Evaluations*,¹ or surgical management of morbid obesity (ie, twice or more the average desirable body weight).²

Obesity can be defined as an excessive accumulation of fat in the body. Measurements of body fat require sophisticated techniques that are not widely available (eg, measurements of body density, determination of

total body fat or water by isotopic or chemical dilution). In clinical practice, anthropometric measurements based on height, weight, and skinfold thickness are recommended.³ For practical purposes, it is generally agreed that obesity is probably present if body weight is 20% or more above "desirable weight" (based on actuarial data on height and body weight at various ages).⁴ For purposes of this discussion, desirable weight is defined as the midpoint of the range for medium-frame individuals as shown in the 1983 Metropolitan Height and Weight Tables (Table).⁵ The first National Health and Nutrition Examination Survey, conducted between 1971 and 1974, found that 28.8 million adults were obese, 8.4 million of whom were severely obese.⁶ The second National Health and Nutrition Examination Survey, conducted between 1976 and 1980, found that 34 million US adults were overweight, 13 million of whom were severely overweight.⁷ *Overweight* was defined as 20% above desirable weight and *severely overweight* as 40% above desirable weight.

Obesity is associated with a number of health hazards. It may impair both cardiac and pulmonary function, modify endocrine function, and cause emotional problems. Hypertension, impaired glucose tolerance, and hypercholesterolemia are more common in overweight individuals than in individuals of normal weight.⁶ Thus, it is not surprising that obesity may contribute to morbidity and mortality in individuals with hypertension, stroke, type II or non-insulindependent diabetes mellitus, some types of cancer, and gallbladder disease.¹ Over the long term, obesity is also considered an independent risk factor for atherosclerotic heart disease.¹

The complex etiology of obesity is in part responsible

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This report is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all the facts and circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and patterns of practice evolve. These reports reflect the views of scientific literature as of December 1987.

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for the difficulty physicians encounter in treating this condition. Despite a multitude of programs designed to treat obesity, success in treatment often is difficult to achieve. If a “cure” for obesity is defined as reduction to desired weight and maintenance of that weight for five years, it is more likely that a person will be cured of most forms of cancer than obesity.⁸

For many persons, obesity is largely a result of life-style, of patterns of eating and physical activity, and of firmly established cultural patterns and social and economic forces.

1983 METROPOLITAN HEIGHT AND WEIGHT TABLES*

Height		Weight, lb		
ft	in	Small Frame	Medium Frame	Large Frame
<i>Men</i>				
5	2	128-134	131-141	138-150
5	3	130-136	133-143	140-153
5	4	132-138	135-145	142-156
5	5	134-140	137-148	144-160
5	6	136-142	139-151	146-164
5	7	138-145	142-154	149-168
5	8	140-148	145-157	152-172
5	9	142-151	148-160	155-176
5	10	144-154	151-163	158-180
5	11	146-157	154-166	161-184
6	0	149-160	157-170	164-188
6	1	152-164	160-174	168-192
6	2	155-168	164-178	172-197
6	3	158-172	167-182	176-202
6	4	162-176	171-187	181-207
<i>Women</i>				
4	10	102-111	109-121	118-131
4	11	103-113	111-123	120-134
5	0	104-115	113-126	122-137
5	1	106-118	115-129	125-140
5	2	108-121	118-132	128-143
5	3	111-124	121-135	131-147
5	4	114-127	124-138	134-151
5	5	117-130	127-141	137-155
5	6	120-133	130-144	140-159
5	7	123-136	133-147	143-163
5	8	126-139	136-150	146-167
5	9	129-142	139-153	149-170
5	10	132-145	142-156	152-173
5	11	135-148	145-159	155-176
6	0	138-151	148-162	158-179

*Source of basic data: 1979 Build Study, Society of Actuaries and Association of Life Insurance Medical Directors of America, 1980. Courtesy of *Statistical Bulletin*, Metropolitan Life Insurance Company.

Some individuals may have a genetic propensity to become obese.⁴ Concern with weight control should begin sufficiently early in life to reduce the risk of developing obesity. Genetic influences appear to have an important role in determining human fatness and obesity.^{9,10} Prevention is the “treatment” of choice. Early identification of individuals genetically at risk can be helpful in targeting those most likely to gain excess weight.

Every obese individual presents a unique problem that is influenced by factors such as degree of excess weight, age, and severity of associated disorders, as well as

developmental patterns, family history, eating and activity patterns, and fat distribution or body shape. If treatment is to be successful, the patient must be strongly motivated to participate in a weight reduction program. Motivators may be psychological (eg, feelings of inadequacy, difficulty in buying fashionable clothing) or physical (eg, joint pain). Substantial weight reduction often can be achieved when the alternative to weight loss entails clearly defined penalties, ie, when excess weight constitutes a health hazard or leads to appreciable morbidity. The physician has a responsibility to explain the rationale for advising weight loss and its importance to health.¹¹ The emphasis on slimness in women in our society, encouraged to a large degree by the advertising media, has created unrealistic expectations of desirable body weight. Preoccupation with extreme slimness can create an environment conducive to anorexia nervosa and/or bulimia in some women.

A realistic goal for weight loss should be established for each individual to prevent disillusionment and, ultimately, abandonment of efforts. A kilogram of adipose tissue provides the energy equivalent of 29 400 kJ (7000 kcal).¹¹ A realistic rate of weight loss should be established for each individual depending on height, weight, age, and degree of obesity. For most patients, a rate of weight loss of about 1% of body weight per week is appropriate. Helping the patient to understand that there is no quick remedy for obesity helps to ensure realistic expectations of weight loss.

Dietary Treatment

Numerous dietary regimens have been devised in an attempt to achieve progressive weight loss in obese individuals. Weight loss occurs only when energy expenditure exceeds intake. Although physical activity plays an important role in balancing the equation between energy intake and expenditure, the mainstay of weight loss is restriction of energy intake.

Fasting

Fasting as a treatment modality for obesity, particularly morbid obesity, has been used for more than 70 years; however, few studies on the overall benefits of weight reduction by this method have been published. Fasting programs conducted under medical supervision have produced variable and sometimes contradictory results.¹² Short periods of fasting have not been successful in morbidly obese subjects; prolonged fasting, at best, is of temporary benefit. Weight is regained by a majority of patients and, in some cases, the former weight is exceeded.¹²

Because total fasting may produce a number of adverse effects, including severe ketosis, hyperuricemia, excessive loss of lean body mass, hyponatremia, hypokalemia, hypoglycemia, neutropenia, alopecia, and increased renal loss of phosphate and magnesium,¹³ close medical supervision is necessary for prolonged total fasting. Although rapid, uninterrupted weight loss occurs with a

prolonged fast, fasting may be hazardous, offers no benefits over other weight-reduction regimens, and does not control weight over an extended period.

Very Low-Energy Diets

The adverse effects associated with total fasting led to the development of “protein-sparing modified fasts” and other very low-energy diets ($<2520 \text{ kJ/d}$ [$<600 \text{ kcal/d}$]). These diets provide protein of high biologic value and are usually prescribed for severely or morbidly obese adults. The purpose of these diets is to produce a rapid weight loss while preserving lean body mass by providing dietary protein or protein with carbohydrate.

Much adverse publicity was associated with liquid protein diets that were promoted to the public in the mid-1970s. Preparations consisting of low-energy pre-digested liquid collagen provided protein of low biologic value and were sold over the counter for the treatment of obesity. By the end of 1977, approximately 60 deaths had been attributed to these diets;¹⁴ 17 of the fatalities were in individuals who had used the liquid protein diets as their sole source of nutrition for longer than two months; ventricular arrhythmias were thought to be the immediate cause of death.¹⁴ More recent evidence¹⁴ indicates that very low-energy diets that provide protein of high biologic value and are supplemented with vitamins and minerals may be safer, when properly supervised, than the now abandoned liquid protein regimens.

Two types of commonly used very low-energy diets are (1) the so-called protein-sparing modified fast that provides approximately 1.5g of protein per kilogram of desirable body weight daily and (2) a liquid formula diet that provides approximately 33 to 70g of protein daily.¹⁵ The former diet eliminates all carbohydrates, and the only source of fat is that obtained from lean meat, fish, and poultry, the only foods permitted in the diet. The liquid diet consists of a milk- or egg-based formula that, in addition to the protein, may include approximately 30 to 45g of carbohydrate and about 2g of fat. Supplementation with vitamins and minerals is required with both types of diets. Comparable results have been achieved with both types of diets.¹⁵ Treatment of more than 10 000 persons has shown that very low-energy diets produce large weight losses, which are directly proportional to the duration of treatment.¹⁶ Weight losses of 20kg in 12 weeks can be attained. These diets should always be supervised by physicians who have knowledge of the metabolic consequences of the regimen.¹⁶

In conclusion, use of very low-energy diets should be restricted to persons with severe obesity; these individuals should have an appropriate cardiac evaluation in the initial screening and remain under medical supervision.¹⁴ The appeal of the impressive weight loss achieved with these diets, however, is severely limited by the seeming inability of patients to sustain their weight loss. Therefore, attention must be directed to maintenance programs after the desired weight loss is achieved.

Balanced vs Unbalanced Low-Energy Diets

The nutritionally balanced low-energy diet provides a conventional distribution of the macronutrients, ie, carbohydrates ($>50\%$ of total energy intake), protein (15% to 20%), and fat ($<30\%$). The usual range of energy intake for such diets is 4200 to 5040 kJ/d (1000 to 1200 kcal/d). When energy intake falls below these levels, it is very difficult to obtain the recommended levels of certain nutrients, such as iron, calcium, magnesium, vitamin B₆, zinc, and copper, without marked alterations in food choices.¹⁷ Therefore, vitamin and mineral supplementation is usually necessary under these circumstances.¹⁸ Since the ultimate goal of any weight-reduction program is to lose weight and maintain the loss, it would appear that a nutritionally balanced low-energy diet composed of conventional foods that are easily obtained and economically feasible would help meet the objective.

Unbalanced low-energy diets place particular emphasis on one or more specific macronutrients while restricting others. Low-carbohydrate diets predominate in this category. The physiological responses of individuals to such diets vary widely and depend on factors such as the nutritional status of the individual, the energy content of the diet, and, to some extent, the individual amounts and proportions of the energy-producing nutrients they contain.¹⁹

There is no evidence that altering the proportions of energy-providing nutrients will have metabolic effects that accelerate or retard the loss of body fat beyond that attributable to the energy deficits generated.¹⁷ The initial rates of weight loss and fluid balance can be affected by the relative proportions of the energy-producing nutrients. For example, diets low in both carbohydrates ($<100 \text{ g}$) and energy value are likely to result in diuresis, which might be construed erroneously as loss of body fat during the initial stages of a weight-reduction program. Although low-carbohydrate diets may be effective as a short-term approach to weight loss, weight is regained once carbohydrate intake is increased. Furthermore, these diets may be associated with fatigue, nausea, orthostatic hypotension, dehydration, and electrolyte imbalance.

Novelty Diets

There are many novelty diets promoted as “revolutionary” or “guaranteed 100% successful” in weight reduction. Most of these diets rely on specific foods or food combinations to facilitate weight loss (eg, the grapefruit diet, the banana and skim milk diet), and they are frequently deficient in important nutrients.²⁰ These diets imply that a specific food or combination of foods selectively oxidizes body fat, increases metabolic rate, or inhibits voluntary food intake.²⁰ Weight can be lost on these diets but not for the reasons stated. In general, these diets cause weight loss by reduction of energy intake, frequently below 4200 kJ/d (1000 kcal/d). Once

the weight is lost, however, little, if any, attention is given to a weight-maintenance plan, and the individual is likely to regain the weight.

Physical Activity

Increasing energy expenditure in addition to decreasing energy intake generally improves results in the management of obesity. Exercise alone, however, may decrease body weight without alterations in the diet except in severely obese patients with hyperplastic adipose tissue. Body fat in these individuals decreases very slowly or not at all with exercise.²¹ The metabolic aspects of exercise and weight reduction pertaining to resting metabolic rate, food intake, and thermogenesis will be discussed briefly.

Resting Metabolic Rate

There has been renewed interest in the question of whether exercise alters the resting metabolic rate (RMR). It has been shown that the RMR and total daily expenditure are elevated in those who are obese.²² Because the RMR is associated with metabolically active tissue, it can be expected that the RMR, and therefore total energy expenditure, will decrease as body cell mass diminishes during a program of weight reduction.²³ Declines in metabolic rates with fasting and semistarvation have been shown to be greater than could be accounted for by the loss of lean body mass alone.²⁴

The rate of weight loss decreases with time when an individual is adhering to a diet in which energy intake is reduced. This has been attributed to the decrease in the RMR that occurs with restriction of energy intake.²² There is a decline in energy expenditure when energy intake is reduced. This may be attributed to the following factors: (1) loss of lean body mass, which results in a decreased RMR; (2) decreased cost of physical activity due to a lower body weight; and (3) lower thermogenic effect of food related to the lower energy intake.²² These factors may contribute to the plateau observed in weight-reduction programs that focus primarily on energy restriction.

There is no general agreement on the effects of exercise on the RMR, but some preliminary data indicate that the decrease in the RMR that normally occurs when individuals are on low-energy diets may be prevented or reduced by incorporating physical activity into the program.

Effect on Food Intake

Studies in rats have demonstrated that low levels of physical activity are commensurate with decreased food intake whereas high levels of physical activity are commensurate with increased food intake.²⁵ However, it is difficult to evaluate the relationship between energy expenditure and energy intake in human studies.

There appears to be very little relationship between energy expenditure and food intake during short periods. During an extended period, however, some degree of regulation does take place. For example, individuals

engaged in strenuous activities (farmers or athletes) have very high levels of energy expenditure with high energy intakes and yet are able to maintain body weight with a low percentage of body fat.²⁵

Studies^{26,27} on the effect of physical activity on energy intake in obese women have shown that moderate exercise was not accompanied by increased energy intake, thus resulting in a negative energy balance and weight loss.

Effect on Thermogenesis

It has been proposed that the thermogenic response to food, which is not more than 10% to 15% of the energy value of the ingested food, interacts with exercise and increases heat production.²⁸ The extent to which this occurs and the differences in thermogenic response between lean and obese individuals are not entirely clear.

Investigations into the potentiation of the thermic effect of food by exercise have produced contradictory results. In an attempt to determine the extent to which exercise enhances the thermic effect of food, one study examined the response of weight-stable lean and obese women to food and two levels of exercise: (1) the same absolute level for all women and (2) a level related to each woman's aerobic fitness.²⁹ The key finding of this study was that exercise potentiated the thermic effect of food for the lean women but not for the obese women despite the fact that similar thermogenic responses were observed to food alone and to exercise alone in both groups. The thermic effect was 2.54 times greater during exercise than at rest for those in the lean group but only 1.01 times greater for those who were obese. Although several investigators have shown that the effect of exercise on the thermic response to meals is potentiated, the effect is moderate. This may have long-term significance, however, for increased total energy expenditure. The potentiation may be defective in obese individuals.¹⁹

Behavioral Modification

Approximately 20 years ago, the behavioral approach to the treatment of obesity attracted much attention and stimulated considerable research and clinical application of this hypothesis. The rationale for this approach is that major changes in eating and exercise behaviors are necessary to ensure long-term weight control and that this must be preceded by a thorough analysis of eating and activity patterns.

Six core characteristics are associated with behavioral therapy:³⁰ (1) an assumption that all behavior is acquired and maintained according to definable principles; (2) a belief that people are best described by their behavior—what they think, feel, and do in specific situations; (3) an attempt to specify treatment measures as precisely as possible and to evaluate outcomes as objectively as possible; (4) an effort to individualize treatment; (5) negotiation of treatment goals between patient and therapist; and (6) continuing and critical assessment of the treatment throughout its course.

Behavioral assessment of obese persons involves attention to (1) the antecedents of eating that promote excessive intake (eg, separating eating from other activities, such as watching television; limiting the amount and accessibility of high-energy foods); (2) slowing the act of eating; and (3) selectively emphasizing the consequences of certain behaviors (eg, rewarding appropriate eating behaviors).³¹

Some studies suggest that behavior therapy is effective for patients who need to lose moderate amounts of weight and to maintain these weight losses for at least one year.³⁰ In comparing effects of behavioral and pharmacologic therapy in obese subjects, patients receiving drugs lost significantly more weight during the treatment phase, but patients who received behavioral therapy were more successful in maintaining their weight losses.³⁰ Thus, for better maintenance of weight loss, it appears that behavioral therapy is superior to short-term pharmacotherapy.

A majority of studies on behavioral treatment of obesity do not include long-term follow-up data. The findings of a five-year follow-up of 36 individuals who participated in a behavioral program for obesity showed a typical pattern of regaining all the weight lost during treatment.³² New approaches that foster maintenance of weight reduction are receiving attention, eg, relapse prevention training, utilization of social support systems, posttreatment contacts with the therapist. It appears that appropriate behavioral strategies during the posttreatment stage can form the basis for lasting weight control.

The benefits of behavior modification may be enhanced when such treatment is combined with other forms of therapy, such as diet and exercise.

Evaluating Commercial Weight-Loss Clinics

Resolution 59, 1983 Annual Meeting, stated, "Any person considering participation in a weight loss program offered by a weight loss clinic should first consult his regular attending physician, or any other independent physician, for a physical examination and an objective professional evaluation of the proposed weight loss program as it relates to the individual's physical condition.

One of the essential factors to consider in evaluating a weight-loss clinic is whether treatment is preceded by careful medical and behavioral assessment. Assessment of baseline eating and exercise behavior is important to determine if the weight problem is due to overeating and/or lack of exercise.³³ Some clinics emphasize only restriction of energy intake.

The degree of obesity should determine the approach to be used for each individual. No one form of treatment is suitable for all obese individuals. Those who require stringent diets, such as the protein-sparing modified fast, should be supervised by physicians who have knowledge of the metabolic consequences of the regimen.

The relationship between the patient and the therapist should be of sufficiently long duration to effect appropriate changes in the patient's life-style, which may

require treatment for a year or more; unfortunately, most patients do not participate in commercial programs long enough for this to occur.³³

The most important consideration in evaluating a weight-loss clinic is the outcome. The probability of a successful outcome can be determined only if information is obtained on the average dropout rate, average posttreatment weight loss, and weight maintenance for one year following treatment. Other factors, such as cost and quality of treatment, should be discussed by the physician and the patient before a decision is made to utilize the services of a weight-reduction clinic.³³

Guidelines For Therapeutic Weight-Control Programs

Relatively little information is available in the medical literature to support very specific recommendations in this area. However, a panel organized under the auspices of the Fourth International Congress on Obesity described the minimum recommended features of a professional weight-control program combining diet, exercise, and behavioral and psychological therapy.³⁴ The guidelines are summarized briefly in this section.

Diet Therapy

Dietary recommendations should be individualized to meet the patient's needs and habits and should be developed through close interaction of patient and therapist. The diet should have the following characteristics: (1) a sound scientific rationale; (2) safety, nutritional adequacy (ie, an acceptably low risk:benefit ratio), and satisfaction of all nutrient needs except energy; and (3) practicality and long-term effectiveness (ie, the diet should be both practical for and applicable to the patient's environment, and it should be conducive to weight maintenance).

Exercise Therapy

As part of a weight-control program, the exercise component should (1) promote increased energy expenditure, (2) promote fat loss and maintenance of lean body mass, (3) be safe for the participating individuals, and (4) promote increases in activity levels within the individual's life-style.

Behavioral and Psychological Assessment

Treatment should focus on methods of acquiring new behaviors that will promote weight loss and long-term maintenance of weight loss. An individual preliminary interview should precede therapy to rule out factors that would preclude successful response to therapy. Certain therapeutic modalities should be included, such as record-keeping of food choices and activity patterns, stimulus control (ie, attention to antecedents of eating that promote excessive intake) and modification of eating behavior, cognitive restructuring, and utilization of social support systems.

Approaches that foster weight maintenance should be included during the posttreatment period (eg, resumption of daily monitoring of dietary and physical activity patterns if weight gain occurs). Once weight is stabilized, long-term follow-up should include annual evaluation.

If weight loss is to be maintained, major changes in life-styles are required. Gradual changes in eating habits and exercise levels must take place, and psychological factors that impinge on these components must be addressed. Such changes can occur only in a comprehensive weight-reduction program, the only effective treatment for obesity.³⁵

Conclusions

Three essential components of a weight-control program are diet, exercise, and behavior modification. Because these elements are interdependent and mutually supportive, a program that incorporates all three is more likely to lead to long-term weight control.

In evaluating commercial weight-loss clinics, it should be ascertained that the proposed weight-loss program is appropriate for the individual's physical condition and that proper medical supervision is provided at the clinic by physicians who have knowledge of the metabolic consequences of the prescribed regimen. An important consideration is a successful outcome, which can be assessed by obtaining information on the average drop-out rate, average posttreatment weight loss, and weight maintenance for at least one year following treatment.

For weight loss to be maintained, gradual changes in eating habits and exercise levels must occur and psychological factors that impinge on these components must be addressed. A comprehensive, long-term weight-control program is the only effective treatment for obesity.

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Urinary Incontinence in Adults

NATIONAL INSTITUTES OF HEALTH

URINARY incontinence, the involuntary loss of urine so severe as to have social and/or hygienic consequences, is a major clinical problem and a significant cause of disability and dependency. Urinary incontinence affects all age groups and is particularly common in the elderly. At least 10 million adult Americans suffer from urinary incontinence, including approximately 15% to 30% of community-dwelling older people and at least one-half of all nursing home residents. The monetary costs of managing urinary incontinence are conservatively estimated at \$10.3 billion annually, and the psychosocial burden of urinary incontinence is great.

Urinary incontinence is a symptom rather than a disease. It appears in a limited number of clinical patterns, each having several possible causes. In some cases, the disorder is transient, secondary to an easily reversed cause such as a medication or an acute illness like urinary tract infection. Many cases are chronic, however, lasting indefinitely unless properly diagnosed and treated.

There is a persistent myth that urinary incontinence is a normal consequence of aging. While normal aging is not a cause of urinary incontinence, age-related changes in lower urinary tract function predispose the older person to urinary incontinence in the face of additional anatomic or physiologic insults to the lower urinary tract or by systemic disturbances such as illnesses common in older people.

Even frail nursing home residents or persons being cared for by family caregivers often have urinary incontinence that can be significantly improved or cured. Persons with urinary incontinence should be alerted to the importance of reporting their symptoms to a health care professional and of asserting their right to proper assessment, diagnosis, and treatment. The first steps to treatment are acknowledgment of the problem and appropriate assessment and diagnosis.

Knowledge of the occurrence, causes, consequences, and treatment of the specific forms of urinary incontinence has increased. While new diagnostic tests have been developed, well-defined guidelines are needed for their application. Similarly, despite numerous new po-

tential therapies, opinions differ widely concerning the best approach to many specific forms of the disorder. The most common treatments include pelvic muscle exercises and other behavioral treatments, local and systemic drug therapies, and a variety of surgical approaches.

The number of patients with urinary incontinence who are not successfully treated remains surprisingly high. This is due to several factors, including underreporting by patients; underrecognition as a significant clinical problem by health providers; lack of education of health providers regarding new research findings; inadequate staffing in the long-term care setting; and the persistent major gaps in our understanding of the natural history, pathophysiology, and most effective treatments of the common forms of urinary incontinence. The amount of basic research as well as research focusing on prevention is meager.

To resolve issues regarding the incidence, causes, treatment, and consequences of urinary incontinence in adults, the National Institute on Aging and the Office of Medical Applications of Research of the National Institutes of Health, in conjunction with the National Institute of Diabetes and Digestive and Kidney Diseases, the National Center for Nursing Research, the National Institute of Neurological and Communicative Disorders and Stroke, and the Veterans Administration, convened a Consensus Development Conference on Urinary Incontinence in Adults on 3-5 October 1988. After a day and a half of presentations by experts in the relevant fields involved with urinary incontinence, a consensus panel consisting of representatives from geriatrics, urology, gynecology, psychology, nursing, epidemiology, basic sciences, and the public considered the evidence and developed answers to the following central questions:

- What is the prevalence and clinical, psychological, and social impact of urinary incontinence among persons living at home and in institutions?
- What are the pathophysiological and functional factors leading to urinary incontinence?
- What diagnostic information should be obtained in assessment of the incontinent patient? What criteria should be employed to determine which tests are indicated for a particular patient?

From the Office of Medical Application of Research, National Institutes of Health, Bethesda, MD.

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- What are the efficacies and limitations of behavioral, pharmacological, surgical, and other treatments for urinary incontinence? What sequences and/or combination of these interventions are appropriate? What management techniques are appropriate when treatment is not effective or indicated?
 - What strategies are effective in improving public and professional knowledge about urinary incontinence?
 - What are the needs for future research related to urinary incontinence?
1. **What is the prevalence and clinical, psychological, and social impact of urinary incontinence among persons living at home and in institutions?**

A. Occurrence and Risk

Estimates of the occurrence of urinary incontinence depend on the nature of the study population and definition of the disorder. Prevalence rates range from 8% to 51%; an estimate of 15% to 30% for community-dwelling older persons seems reasonable, and of these, 20% to 25% may be classified as severe. Prevalence rates are twice as high in women as in men, and are higher in older than in younger adults. Though these community rates are alarmingly high, rates in nursing homes are even higher. Half or more of the 1.5 million Americans in nursing homes suffer from urinary incontinence.

Little is known about the natural history of urinary incontinence, including age at onset, incidence rates, progression, and spontaneous remission. Limited data exist on associated morbidity and functional impairment. To date, most studies have been conducted in whites, and data are needed on the occurrence in non-white ethnic groups.

Though urinary incontinence is a symptom of many conditions, defining risk factors would be extremely useful for identifying high-risk persons and remediable environmental causes. While age, gender, and parity are established risk factors, many other factors have been suggested but not rigorously proven. These include urinary tract infection, menopause, genitourinary surgery, lack of postpartum exercise, chronic illnesses, and various medications. Risk factor identification is essential for a concerted effort at prevention.

B. Clinical, Psychological, and Social Impact

In the Community

Because only about half of the people with incontinence in the community have consulted a doctor about the problem, the true extent and clinical impact of urinary incontinence is not known. Rashes, pressure sores, skin and urinary tract infections, and restriction of activity are some of the problems that could be prevented or treated if the underlying incontinence were brought to medical attention. Many people with incontinence turn prematurely to the use of absorbent materials without having their difficulty properly diagnosed and treated.

The psychosocial impact of incontinence in the community falls on individuals and their care providers. Studies of women show that the condition is associated with depressive symptoms and leads to embarrassment about appearance and odor, although such reactions

may be related more to illness than to incontinence. Excursions outside the home, social interactions with friends and family, and sexual activity may be restricted or avoided entirely in the presence of incontinence. Spouses and other intimates also may share the burden of this condition. A highly conservative estimate of the direct costs of caring for persons with incontinence of all ages in the community is \$7 billion annually in the United States.

In Nursing Homes

Many physicians fail to recognize the clinical impact of urinary incontinence in nursing homes, and very few nursing home residents with incontinence have had any type of diagnostic evaluation. In this setting, fecal incontinence, physical and mental impairment, pressure sores, and urinary tract infections are commonly associated with urinary incontinence, but cause-and-effect relationships are not clear. Many nursing home residents who are incontinent are managed with indwelling catheters, which carry an increased risk of significant urinary tract infection, and the use of such devices varies widely. The odor of urine that permeates many nursing homes can be repellent to residents, staff, and potential visitors. Managing those with incontinence presents a major problem to insufficient and often untrained staff. The annual direct cost of caring for incontinence among nursing home patients is approximately \$3.3 billion.

2. **What are the pathophysiological and functional factors leading to urinary incontinence?**

Continence requires a compliant bladder and active sphincteric mechanisms, but that maximum urethral pressure always exceeds intravesical pressure. Normal voiding requires sustained and coordinated relaxation of the sphincters and contraction of the urinary bladder.

These functions are regulated by the central nervous system through autonomic and somatic nerves. The system requires the integration of visceral and somatic muscle function and involves control by voluntary mechanisms originating in the cerebral cortex. These voluntary mechanisms are learned and culturally prescribed (ie, toilet training).

Incontinence can be produced by any pathologic, anatomic, or physiologic factor that causes intravesical pressure to exceed maximum urethral pressure. Intravesical pressure can be raised by involuntary detrusor contractions (unstable bladder or detrusor hyperreflexia), by acute or chronic bladder overdistension (urinary retention with overflow), or by an increase in intra-abdominal pressure. Similarly, a decrease in urethral pressure may occur as a result of uninhibited sphincter relaxation (unstable urethra), loss of pelvic floor support (genuine stress incontinence), and urethral wall defects from trauma, surgery, or neurologic disease.

Subtypes of Urinary Incontinence

The most commonly encountered clinical forms of urinary incontinence in adults are stress incontinence, urge incontinence, overflow incontinence, and a mixed form. In stress incontinence, dysfunction of the bladder outlet leads to leakage of urine as intra-abdominal pres-

sure is raised above urethral resistance while coughing, bending, or lifting heavy objects. Volume of urine leakage is generally modest at each occurrence and, in uncomplicated cases, postvoid residual volume is low. Stress incontinence has many causes, including direct anatomic damage to the urethral sphincter (sphincteric incontinence), which may lead to severe, continuous leakage, and weakening of bladder neck supports, as is often associated with parity.

Urge incontinence occurs when patients sense the urge to void (urgency) but are unable to inhibit leakage long enough to reach the toilet. In most, but not all, cases, uninhibited bladder contractions contribute to the incontinence. Urine loss is moderate in volume, occurs at several hour intervals, and postvoid residual volume is low at several hour intervals. Among the causes of urge incontinence are central nervous system lesions such as stroke or demyelinating disease, which impair inhibition of bladder contraction, and local irritating factors such as urinary infection or bladder tumors. In many cases of urge incontinence, no specific etiology can be identified despite detailed clinical and laboratory evaluation.

An important variant of urge incontinence is reflex incontinence, in which urine is lost due to uninhibited bladder contractions in the absence of the symptoms of urgency. In addition, many persons suffer from very frequent symptoms of urgency and are only able to remain continent by conducting their activities in the proximity of restrooms.

Overflow incontinence occurs when the bladder cannot empty normally and becomes overdistended, leading to frequent, sometimes nearly constant, urine loss. Causes include neurologic abnormalities that impair detrusor contractile capacity, including spinal cord lesions, and any factor that obstructs outflow, including medications, tumors, benign strictures, and prostatic hypertrophy.

Many cases of urinary incontinence fall into the mixed category, displaying some aspects of more than one of the major subtypes, both clinically and on extensive laboratory evaluation.

The term "functional" incontinence is applied to those cases in which the function of the lower urinary tract is intact, but other factors such as immobility or severe cognitive impairment result in urinary incontinence.

It should be clear that urinary incontinence can be caused by multiple and often interacting conditions. Of particular importance are the transient or reversible factors such as infection, delirium, and drugs. These causes, which may be common in the elderly patient, should be carefully considered in the pathophysiology of urinary incontinence.

There are age-related changes in the lower urinary tract that increase its vulnerability to both chronic and transient factors. Increases in uninhibited contractions, nocturnal fluid excretion, and prostate size, accompanied by decreases in bladder capacity and flow rate, all lead to greater susceptibility to urinary incontinence in the face of stresses associated with disease, functional impairment, or environmental factors. In older persons,

cognitive decline, musculoskeletal impairments, and restricted access to toilets may all convert the marginally continent system to incontinence.

3. What diagnostic information should be obtained in assessment of the incontinent patient? What criteria should be employed to determine which tests are indicated for a particular patient?

Evaluation and therapy must be tailored to the individual, taking into account clinical, cognitive, functional, and residential status in addition to the potential for correcting the problem. Just as a child is not simply a young adult, octogenarians differ from persons in their forties. Patients with stress urinary incontinence are quite dissimilar from those with uninhibited contractions and unstable bladders. Proper diagnosis and active case finding are imperative.

Core Evaluation

History

The evaluation of all patients with incontinence requires a thorough history, including medical, urologic, gynecologic, and neurologic assessment, with particular attention to those factors that influence bladder function. The duration, frequency, volume, and type of incontinence should be described and validated by a voiding diary. Other important information includes associated illnesses, previous operations, and current medications.

Physical Examination

Physical examination is required, with emphasis on mental status; mobility and dexterity; and neurologic, abdominal, rectal, and pelvic findings. A provoked full-bladder stress test is recommended. Since prostate enlargement is often asymmetric, the size of the prostate as estimated on rectal exam may be misleading when evaluating the possible contribution of prostatic hypertrophy to urinary obstruction.

In addition to the history and physical examination, core measurements to be obtained in all patients are urinalysis, serum creatinine or blood urea nitrogen, and postvoid residual urine volume. Other tests such as urine culture, blood glucose, and urinary cytology may be useful.

Based on the findings from the core evaluation, a decision for treatment or more definitive evaluation is made, taking into consideration the type and degree of incontinence.

Specialized Studies

The tests currently available for specialized study include:

- Cystometrogram—to be used as the basic study in cases requiring more than core evaluation, should be accompanied by measurement or estimation of abdominal pressure.
- Electrophysiologic sphincter testing (EMG).
- Ultrasound of the bladder or kidneys may detect residual urine or hydronephrosis.
- Cystourethroscopy with or without cytology is indicated in patients with hematuria or the recent onset of

urgency or urge incontinence who are at increased risk for carcinoma.

- Uroflowmetry has wide application in the evaluation of obstructive disease in men but a limited role in the evaluation of women.
- Videourodynamic evaluation requires special expertise. Its role is limited to the more elusive incontinence problems.
- Urethral pressure profilometry is a controversial test. Its predictive value has been questioned, and it requires further validation before it can be recommended for widespread use.

These numerous noninvasive and invasive tests must be used selectively. Examples of patients rarely requiring further diagnostic testing after the core examination include the young woman with classic stress incontinence or the 80-year-old woman with a recent stroke and the new onset of urge incontinence. Patients with stress incontinence and a significant urge component or those in whom previous operations have failed may require combined cystography and fluoroscopy with a complete urodynamic evaluation. Some patients with urge or mixed incontinence, or those who are not helped by empiric therapy or operation, also will require more complete urodynamic testing. Some patients may not be candidates for sophisticated studies due to inability to cooperate or a poor prognosis for correction. Armed with this information, the investigating physician should be able to reach an accurate diagnosis leading to appropriate therapy.

4. What are the efficacies and limitations of behavioral, pharmacological, surgical, and other treatments for urinary incontinence? What sequences and/or combination of these interventions are appropriate? What management techniques are appropriate when treatment is not effective or indicated?

A. General Principles of Treatment

- All persons with incontinence should be considered for evaluation and treatment.
- Treatment decisions should be based on a diagnosis made after a reasonable evaluation of anatomy and function of urine storage and emptying.
- Treatment for incontinence is given to a specific individual, whose personality, environment, expectations, and clinical status are important determinants of treatment modalities to be used and the order of their application.
- The patient requires sufficient information and explanation to be able to make a choice among therapeutic options.
- Environmental constraints in the community or in an institution that may impede treatment are common, and strategies to circumvent impediments are a part of the therapy.
- In particular, availability of adequate numbers of properly constructed public toilets is an important adjunct to incontinence management.

B. Pharmacologic Treatment

Most drugs currently used in managing the varied

causes of urinary incontinence have not been studied in well-designed clinical trials. Nevertheless, it has been suggested that many agents are beneficial, especially for urge incontinence due to uninhibited detrusor contractions. For these patients, drugs that increase bladder capacity can be helpful. One attendant risk is the precipitation of retention. Accordingly, outlet obstruction or a weak detrusor should be looked for as possible contraindications to these agents.

Bladder Relaxants

These agents are generally used for urge incontinence:

- **Anticholinergics**

Anticholinergic agents inhibit detrusor contraction, and may produce increased bladder capacity and delay and reduction in amplitude of involuntary contractions. Propantheline is frequently effective, although high doses may produce unacceptable side effects such as dry mouth, dry eyes, constipation, confusion, or precipitation of glaucoma.

- **Direct Smooth Muscle Relaxants**

These antispasmodics work directly on bladder muscle, but they have a mild anticholinergic effect as well. A randomized, double-blind, placebo-controlled study has shown benefit with oxybutynin in patients with detrusor instability, some but not all of whom were incontinent. Favorable reports also exist about flavoxate and dicyclomine, the other two agents in this class.

- **Calcium Channel Blockers**

These agents, used clinically for cardiovascular indications, have a depressant effect on the bladder as well, but they have not been studied rigorously for the treatment of urge incontinence in comparison with other agents. In the patient being considered for treatment for heart disease, the bladder effects of calcium antagonists must be kept in mind for both their potential benefit as well as risk of retention.

- **Imipramine**

This tricyclic antidepressant has anticholinergic and direct relaxant effects on the detrusor and an alpha adrenergic enhancing (contracting) effect on the bladder outlet, all of which enhance continence. Although imipramine is commonly used, potential side effects of postural hypotension and sedation as well as all peripheral anticholinergic effects make caution imperative when considering this agent in older persons.

Bladder Outlet Stimulants

Alpha adrenergic agonists, used in treatment of stress incontinence, produce smooth muscle contraction at the bladder outlet and may improve continence. Pseudoephedrine and ephedrine both are active, but phenylpropanolamine has been used most often, and objective benefit by urodynamic study has been shown.

Estrogens

Because urinary incontinence increases in women with increasing age, and because menopause results in estrogen deficiency, estrogen replacement has been thought to be helpful for urinary incontinence. Several studies have shown no improvement in stress inconti-

nence, but women with postmenopausal urge incontinence, urgency, and frequency have shown improvement. Long-term use should be considered in view of other risks and benefits.

C. Surgery

Surgery is particularly effective in treatment of pure stress incontinence associated with urethrocoele. A variety of surgical techniques for the transvaginal or trans-abdominal suspension of the bladder neck yield a success rate between 80% and 95% in appropriately selected patients with stress incontinence at one-year follow-up. Long-term results require study. When incontinence in men is secondary to outflow obstruction and chronic retention is secondary to prostatic enlargement, it is best treated with prostatectomy.

In addition, there are several specialized and more extensive surgical procedures. When incontinence is due to intrinsic sphincter dysfunction, which may occur after the surgical trauma of radical prostatectomy or sphincter denervation, the compression action of the sphincter is lost. An implantable prosthetic sphincter can restore this compression. Continence is restored in 70% to 90% of patients in various series. A complication rate greater than 20% includes erosion of the urethra, infection, and mechanical failure. Reoperations are frequently required.

Urethral sling procedures pass a ribbon of fascia or artificial material beneath the urethra. The sling, fixed to the anterior body wall, serves to elevate and compress the urethra, restoring continence in 80 % of patients. Bladder augmentation with isolated bowel segments will increase bladder capacity and vent excessive bladder pressure. This procedure is limited to certain specific bladder problems such as the contracted bladder of neurologic disease or tuberculosis. Bladder replacement with continent diversion can also be offered to the cystectomy patient.

There are no simple procedures to control bladder instability or sensory urgency. When incontinence is due to a mixture of stress and urge, pharmacologic or behavioral treatment may be employed in conjunction with surgery, but results are not as good as when stress incontinence exists alone.

Selection of patients for surgical procedures depends upon the diagnosis and upon the condition of the patient. The frailty of the patient, the condition of tissues, and the state of nutrition bear on the ability to heal. The severity of symptoms must be considered in relation to the risk the patients must undertake for their surgical correction. Finally, such factors as the durability of the treatment and the incidence of complications must also be considered in choosing a treatment option.

D. Behavioral Techniques

Behavioral techniques increase the patient's awareness of the lower urinary tract and environment and can enhance control of detrusor and pelvic muscular function. Such techniques are participatory, relatively noninvasive, and generally free of side effects, and they do not limit future options. They do require time, effort, and continued practice. Some patients become dry, while a

larger number experience important reduction of wetness, and others receive no benefit. Those who appear to benefit are highly motivated individuals without cognitive deficits. Men and women with stress and urge incontinence have benefited, whereas patients with severe sphincter damage (such as in postradical prostatectomy with constant leakage) generally do not benefit.

Behavioral techniques should be offered as a choice to patients who are motivated to put in the time and effort and wish to avoid a more invasive procedure. Commonly employed techniques include:

- *Pelvic muscle exercises* strengthen the voluntary peri-urethral and pelvic floor muscles, the contraction of which exerts a closing force on the urethra. These techniques have been emphasized for women with stress incontinence but appear to be useful in men as well. Benefit has been reported in 30% to 90% of women, but criteria for improvement differ among studies. Patients with mild symptoms may improve most. Continued exercise is required for continued benefit.
- *Biofeedback* is a learning technique to exert better voluntary control over urine storage. Biofeedback uses visual or auditory instrumentation to give patients moment to moment information on how well they are controlling the sphincter, detrusor, and abdominal muscles. After such training, successful patients typically learn to perform the correct responses relatively automatically. Patients with urinary incontinence are trained to relax the detrusor and abdominal muscles and/or contract the sphincter, depending upon the form of incontinence. When used in patients with stress and/or urge incontinence, biofeedback has been shown to result in complete control of incontinence in approximately 20% to 25% of patients and to provide important improvement in another 30%. There are two caveats: the degree of improvement is variable, and long-term follow-up data are not available. It is important to recognize that biofeedback requires sophisticated equipment and training. The benefit of adding biofeedback to pelvic muscle exercise regimens has not been adequately evaluated.
- *Bladder Training* instructs patients to void at regular short intervals, usually hourly during the day, and then at progressively longer intervals of up to 3 hours over a training period of a few to a dozen weeks. Bladder training appears to be effective in reducing the frequency of stress and urge incontinence. Studies have indicated cure rates of 10% to 15% and improvement in the majority of patients.
- *Behavioral techniques in the nursing home.* For institutionalized elderly, almost any consistent attention to the problem, including bladder training and frequent scheduled checks for dryness appears to reduce incontinence in at least some patients. Another technique applicable in the nursing home is prompted voiding, in which frequent (one to two hourly) checks for dryness are made, reminding the patient to void and praising success.

E. Staging of Treatment

As a general rule, the least invasive or dangerous procedures should be tried first. For many forms of incontinence, behavioral techniques meet this criterion. When behavioral techniques do not achieve the desired result, pharmacologic treatment can be initiated. Clear indications for surgical intervention must be respected, however, and surgical treatment should not be withheld inappropriately. Overflow incontinence due to prostatism and urge incontinence due to carcinoma of the bladder or prostate must be recognized and treated promptly. After having been informed of surgical and nonoperative options, the patient who is a surgical candidate and wants prompt treatment (eg, as in the case of stress incontinence) should be operated on. In patients with mixed incontinence, a combination of surgery, behavioral techniques and pharmacotherapy may be helpful.

F. What management techniques are appropriate when treatment is not effective or indicated?

For patients who have not been successfully treated, management plans must be developed to maximize their well-being. Even when permanent improvement is not expected, techniques such as frequent toileting and reminders may be useful in reducing the impact of the patient's incontinence. Careful evaluation of the timing and pattern of incontinence may suggest helpful changes such as bedtime fluid restriction, provision of easier access to toilet facilities, and temporary or permanent arrangements for protection of the patients, their clothing, and environment.

Currently available modes of protection include absorbent pads or garments, indwelling catheters, and external collection devices such as condom catheters. Absorbent pads or garments provide comfort and convenience when used temporarily in conjunction with therapy; no method is entirely satisfactory for long-term use. For long-term use with incapacitated patients, absorbent materials are expensive, require personnel time, and can be associated with pressure sores when circumstances prevent meticulous attention to prompt changes.

For men, external collection devices are less expensive and less time-consuming for patient and caregiver, but they are associated with increased incidence of urinary tract infection and other complications. Practical external collection devices for women are not generally available.

Indwelling urethral or suprapubic catheters may be necessary for selected patients, but almost invariably lead to bacteriuria within a few weeks and have been associated with sepsis.

5. What strategies are effective in improving public and professional knowledge about urinary incontinence?

There have been limited efforts to inform the public and professionals about urinary incontinence. The effectiveness of these strategies has not been evaluated. Incontinence education, therefore, must rely on methods that have been used in other areas of health education. Effective strategies to improve public and professional awareness need to be developed, implemented, and evaluated.

Negative societal attitudes about urinary incontinence have been a barrier to increasing public and professional knowledge. The scientific study of incontinence and the dissemination of research findings will help professionals and laypersons realize that loss of continence need not be a condition that is inevitable or shameful.

Strategies for Improving Public Knowledge

Providing accurate information on the management of incontinence to persons with this problem and their families is a challenging and important task. Studies suggest that only half of the people with incontinence report their condition to a physician. Strategies that will reach the largest number of people will be effective in encouraging them to seek professional help. These include informative newspaper and magazine articles, radio and television programs, and special education programs in senior centers.

One innovative suggestion that deserves consideration is the mandatory labeling of all absorbent products, informing the public that persistent urinary incontinence should be evaluated and that effective treatments are available.

Strategies for Improving Professional Knowledge

There is an urgent need to educate professionals and paraprofessionals about urinary incontinence.

First and foremost, information on urinary incontinence should be included in the core curricula of undergraduate and graduate professional schools. Schools of nursing should consider the feasibility of educating specialists on incontinence care, who can serve as expert advisers to health care professionals.

To increase practitioners' knowledge of this important condition, continuing education courses focusing on the types of incontinence and appropriate diagnostic measures and treatment should be offered. Professionals most likely to provide care to people with incontinence should be encouraged to attend these courses.

Education on the topic of urinary incontinence should also be a part of the training programs for paraprofessional students such as licensed vocational nurses, nurses aides, and auxiliary workers in the community. Because urinary incontinence is a problem of great magnitude in long-term care settings, special emphasis should be placed on educating nurses aides.

Last, coordinated care for people with incontinence will be facilitated by encouraging alliances among all professionals responsible for caring for people with incontinence.

6. What are the needs for future research related to urinary incontinence?

The Consensus Development Conference on Urinary Incontinence in Adults has provided an overview of current knowledge on the etiology, pathophysiology, sequelae, and management of this prevalent clinical problem. Although information on incontinence is increasing, this field has long been neglected, and numerous gaps exist in our knowledge. While many controversies were addressed, numerous questions were identified

that await answers and thus serve as the focus for future research directions. These issues will require the collaborative input of investigators from the spectrum of relevant disciplines and the rigorous application of appropriate research principles.

Directions for future research:

- Basic research on the mechanisms underlying the etiology, exacerbation and response to treatment of specific forms of urinary incontinence and urgency.
- Epidemiologic studies with emphasis on elucidation of risk factors for development of urinary incontinence, its occurrence in specific populations (particularly males and nonwhites), and the natural history of the various clinical and physiologic subtypes.
- Studies of strategies to prevent urinary incontinence.
- Randomized clinical trials, including longitudinal studies in well-specified populations, of algorithms for the systematic assessment of patients with incontinence and of specific behavioral, pharmacologic, and surgical treatment, either alone or in combination.
- Development of new therapies, including pharmacologic agents with greater specificity for the urinary tract and new behavioral and surgical strategies and other innovative techniques, including electrical stimulation.

Conclusions

- Urinary incontinence is very common among older Americans and is epidemic in nursing homes.
- Urinary incontinence costs Americans more than \$10 billion each year.
- Urinary incontinence is not part of normal aging, but age-related changes predispose to its occurrence.
- Urinary incontinence leads to stigmatization and social isolation.
- Of the 10 million Americans with urinary incontinence, more than half have had no evaluation or treatment.
- Contrary to public opinion, most cases of urinary incontinence can be cured or improved.
- Every person with urinary incontinence is entitled to evaluation and consideration for treatment.
- Most health care professionals ignore urinary incontinence and do not provide adequate diagnosis and treatment.
- Inadequate nursing home staffing prohibits proper treatment and contributes to the neglect of nursing home residents.
- Medical and nursing education neglect urinary incontinence. Curriculum development is urgent.
- A major research initiative is required to improve assessment and treatment for Americans with urinary incontinence.

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Relationship of Syphilis to Drug Use and Prostitution: Connecticut and Philadelphia, Pennsylvania

CENTERS FOR DISEASE CONTROL

SINCE 1984, in many areas of the United States, reported rates of syphilis have greatly increased.¹ Between 1984 and 1987, annual rates of syphilis (primary and secondary) increased 70% in the state of Connecticut and 74% in the city of Philadelphia (Figure 1). These

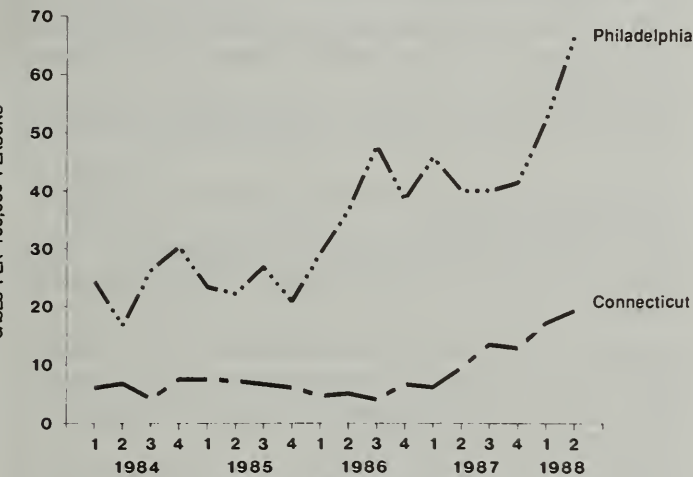


Figure 1
Cases of primary and secondary syphilis, by quarter—Connecticut and Philadelphia, 1984-88.

trends have continued in 1988; in the first quarter of this year, annualized rates increased by 70% in Connecticut and by 25% in Philadelphia compared with 1987 annual rates. Investigations were conducted at these two sites to identify factors associated with this increase.

In Philadelphia and Connecticut, over 80% of all newly diagnosed patients with early syphilis are interviewed and counseled. Cases are detected through reporting by public clinics and private health-care providers and through laboratory screening. During the interviews, information is collected about patients' life-styles to help locate sexual contacts. In Philadelphia and Connecticut, records from these interviews were abstracted and analyzed for the years 1985-87. In Connecticut, all interviews of persons with primary and secondary syphi-

*Abstracted interviews consisted of all those conducted in the first three months of 1985 and 1986 and a systematically selected sample of two-thirds of interviews conducted in the first three months of 1987.
Morbidity and Mortality Weekly Reports, Vol. 37, Nos. 46, 49 and 50, 1988.

lis were abstracted: in Philadelphia, a sample of interviews* was chosen that involved persons with primary, secondary, and latent syphilis present less than one year.

At both sites during the three-year period, the proportion of men with syphilis who reported sexual contact with men decreased substantially. In Connecticut, the proportion of men with syphilis who reported being homosexual or bisexual decreased from 38% (48/126) in 1985 to 11% (21/197) in 1987; in Philadelphia, the percentage declined from 53% (49/93) to 18% (25/137) during this three-year period.

In contrast, recorded use of illicit drugs and reported prostitution or contact with a prostitute among heterosexual syphilis patients increased greatly during this period. Among females at both study sites, the proportion reporting to be prostitutes increased more than threefold and the proportion reporting use of drugs increased more than sixfold (Figure 2). Heterosexual

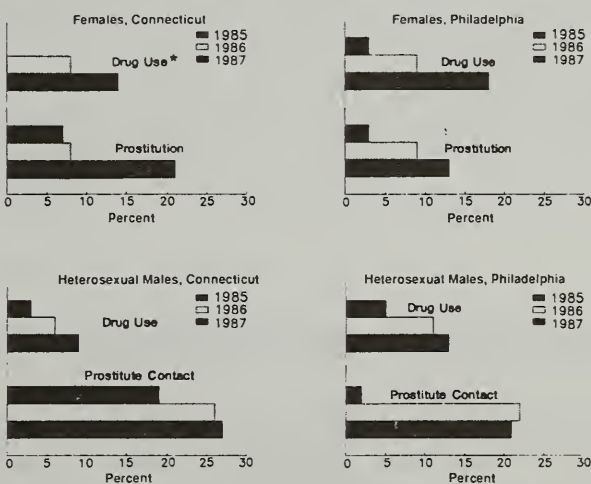


Figure 2
Reported illicit drug use and prostitution among syphilis patients, by category and year—Connecticut and Philadelphia, 1985-87.

male syphilis patients showed similar but smaller increases in recorded drug use. Prostitute contact by this group occurred more frequently in Connecticut than in Philadelphia but increased at both sites.

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Editorial Note: Although prostitution has long been associated with syphilis (and other sexually transmitted diseases),² it appears to have been relatively unimportant in the overall epidemiology of syphilis in the United States during the last two decades.^{3,4} Drug use has only recently been associated with the spread of syphilis.¹ Since drug use and prostitute contact were not recorded systematically on case interview forms, the true frequency of these behaviors among syphilis patients is probably underestimated. This underreporting of these behaviors, if combined with changing interviewers' perceptions, could bias the findings in Connecticut and Philadelphia. However, the consistency between the two sites and the magnitude of the increase in reporting of prostitution and drug use suggest that the trends observed in Connecticut and Philadelphia reflect real changes in the epidemiology of syphilis.

The decrease in the proportion of male syphilis patients who are homosexual/bisexual has been noted in California and New York City,⁵ in outbreaks in Manitoba⁶ and Florida,⁷ and in a sample of states with recent increases in syphilis.⁸ In the Florida outbreak, prostitutes were also found to be an important risk group. The results of the studies in Connecticut and Philadelphia support these other findings and suggest that the emergence of syphilis among prostitutes, drug users, and their sexual contacts may be a widespread national phenomenon.

The possibility of an increase in syphilis among persons in these risk groups has important implications for the control of syphilis and other sexually transmitted diseases, including human immunodeficiency virus (HIV) infections. Prostitutes tend to have large numbers of anonymous sexual partners who are difficult to locate by traditional methods of partner notification. Prostitutes who also frequently use intravenous (IV) drugs and, in

some parts of the country, those with a history of IV-drug use have high rates of infection with HIV.⁹ Recent studies have suggested that sexually transmitted diseases that cause genital ulcers, such as syphilis, greatly increase the likelihood that HIV infection, when present, will be transmitted.¹⁰⁻¹² To limit the spread of syphilis, which may also help limit the spread of HIV, public health officials may need to modify current control methods to better identify and treat syphilis-infected prostitutes, drug users, and their sexual contacts.¹

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State and Local Influenza Immunization Program Activities

INFLUENZA prevention and control efforts in the United States have relied on cooperation between federal, state, and local public health agencies and private sector providers. Since the 1979-80 influenza season, public sector resources for influenza control have been provided primarily by state and local health agencies.

Between the 1985-86 and 1986-87 influenza seasons, the number of state and local projects offering influenza vaccine increased markedly. During the 1985-86 influ-

enza season, 20 of 63 federal immunization grant-supported localities reported purchasing approximately 1,710,024 doses of influenza vaccine for use in public clinics. During the 1986-87 influenza season, 36 localities reported purchasing 2,179,485 doses of influenza vaccine. Compared with the previous year, the activities in 1986-87 represented increases of 80% in project participation and 27% in the number of doses purchased.

Programs in Allegheny County, Pennsylvania, and in California and Vermont illustrate state and local efforts

to improve influenza vaccine coverage.

Allegheny County, Pennsylvania. During the 1986-87 influenza season, the Allegheny County Health Department conducted expanded outreach clinics to immunize high-risk persons against influenza. Of the 10,200 persons residing in nursing home facilities, 8529 (84%) received vaccine provided by the health department. Previous immunization coverage levels in Allegheny County nursing homes ranged from a low of 36% in the 1979-80 influenza season to a high of 71% during the 1985-86 season. An additional 43,926 doses were administered in health department clinics, hospital outpatient departments, community clinics, and senior citizen facilities. An estimated 21% of the 210,000 persons >65 years of age who were not in long-term-care facilities received publicly purchased vaccine. Allegheny County coordinated the development of a coalition involving the American Lung Association (ALA) of Western Pennsylvania and other health-care organizations that conducted surveys to measure the impact of and coverage levels for their programs. A telephone survey conducted by the ALA at the conclusion of the 1986-87 influenza season showed overall influenza vaccination rates of 32% in noninstitutionalized persons aged >65 years in the general population. The ALA publicized the recommendations and distributed educational material to high-risk groups.¹

California. The State of California, through the California Department of Health Services (CDHS), distributed over 481,000 doses of influenza vaccine, of which over 350,000 doses were administered to approximately 12% of California residents >65 years of age. This program, in operation since 1974, is funded entirely through state general revenue funds. The CDHS distributes vaccine to 59 county and municipal health departments. Fees up to \$2.00 may be charged by local units to defray administrative costs. Vaccine is offered at clinics to all persons >55 years of age and to persons of any age with certain chronic illnesses. Staff for outreach clinics and nursing home programs is provided jointly by California chapters of the American Red Cross and state and local health departments.

Vermont. The Vermont Department of Health receives a yearly grant from Blue Cross/Blue Shield of Vermont to support the purchase of influenza vaccine for an immunization program for persons >60 years of age and persons of all ages with high-risk conditions. Vaccine is distributed to home health agencies and visiting nurse associations that provide staffing and clinic coordination. Area Offices on Aging provide additional coordination and publicity through a newsletter distributed to senior citizens of Vermont. During the 1987-88 influenza season, approximately 11,000 persons received influenza vaccine through this program.

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ment of Health Services. RL Vogt, MD, State Epidemiologist, Vermont Department of Health. Division of Immunization, Center for Prevention Services, CDC.

Editorial Note: Older persons and those with certain chronic health problems are at increased risk for complications of influenza infection. Target groups for influenza immunization include children and adults with cardiovascular or renal disease, metabolic diseases (including diabetes mellitus), severe anemia, or compromised immune function; residents of chronic-care facilities; health-care professionals caring for high-risk patients; and household contacts of high-risk persons.²

As many as 50,000 excess deaths are caused by influenza in the United States during epidemic years. Although influenza vaccine can substantially reduce influenza-associated morbidity and mortality, only about 20% of high-risk persons are immunized annually. To increase coverage, many state and local health departments have collaborated with private sector groups to develop special influenza vaccination programs such as those reported above. In addition, in October 1988, CDC, in collaboration with the Health Care Financing Administration, awarded demonstration grant funds to nine programs to assess the cost effectiveness of furnishing influenza vaccine to Medicare part B beneficiaries.

In the hospital setting, influenza vaccine should be offered to high-risk persons between September and February.² Although other organized vaccination campaigns for high-risk persons are optimally undertaken in November, health-care providers should make every effort to ensure that high-risk persons are immunized during routine health-care contacts during the fall and early winter. Studies suggest that at least 40%-55% of persons who are at high risk or who died of influenza and pneumonia may have received care in a health-care institution during the previous year; at least 75% of these persons have attended outpatient clinics but failed to receive influenza vaccine when vaccines should have been routinely available.²⁻⁴ Recognizing these missed opportunities is important in improving coverage levels in high-risk groups.

Because of its substantial health impact, influenza is one of the most important vaccine-preventable diseases of adults. All providers of health care to adults should take every opportunity to review the immunization status of patients and, when indicated, offer their patients influenza vaccine and other vaccines (pneumococcal, tetanus/diphtheria toxoids, measles-mumps-rubella, and hepatitis B) appropriate for adults.

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Hypothermia Prevention

FROM 1976 through 1985, 7,450 deaths were caused by exposure to cold* in the United States (Figure 1). Of health effects associated with cold exposure, hypothermia—defined as a core body temperature of $\leq 35^{\circ}\text{C}$ ($\leq 95^{\circ}\text{F}$)—is the most commonly fatal syndrome. Persons ≥ 60 years of age are particularly susceptible to hypothermia and account for more than half of all deaths.¹ Younger persons subjected to overwhelming cold stress are also vulnerable.² Although deaths attributable to hypothermia occur infrequently in children, infants less than one year of age are at relatively high risk. Rates of death from hypothermia are generally higher in males than in females, but these differences are less substantial in children and the elderly.³

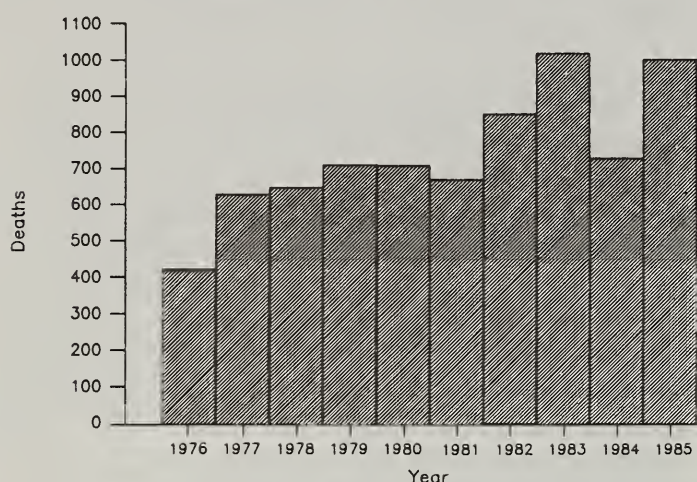


Figure 1

Deaths attributable to excessive cold exposure—United States, 1976-1985.

Persons with hypothyroidism are at increased risk for hypothermia.⁴ In addition, a variety of drugs, principally sedative-hypnotics, may predispose users to hypothermia; ethanol and neuroleptic medications particularly increase susceptibility to cold.²

As the body temperature of a cold-exposed person decreases, impaired consciousness, confusion, or disorientation may occur. Because mental status is altered, a mildly hypothermic persons may fail to take appropriate corrective measures to lessen exposure. In response to

the decline in core temperature, vasoconstriction (causing pallor) and shivering occur. However, shivering decreases markedly in severe hypothermia because thermoregulation becomes impaired. Severely hypothermic persons lose consciousness and develop shallow respirations. Ventricular fibrillation and death may follow.²

Reported by: Health Studies Br, Division of Environmental Hazards and Health Effects, Center for Environmental Health and Injury Control, CDC.

Editorial Note: This preliminary study of mortality suggests a trend toward increased incidence of hypothermia. Although age-adjusted rates are required to properly evaluate the hypothesis that mortality due to effects of cold is increasing, the crude numbers of deaths (Figure 1) strongly suggest such a trend.

Hypothermia prevention programs should focus on persons particularly susceptible to hypothermia and those likely to be subjected to unusual cold stress. Persons caring for the elderly should be alerted to hypothermia's symptoms and signs, and elderly persons living alone should be visited frequently. Since adequate caloric intake is important in preventing hypothermia, programs designed to improve nutrition in the elderly may also be helpful. Programs that ensure home heating for the elderly may also help prevent hypothermia.

Younger persons likely to be subjected to cold stress (eg, skiers and hikers) should be educated concerning the need for adequate clothing and the importance of abstaining from alcohol use during prolonged cold exposure. Shelter should be offered to homeless persons who would otherwise sleep outdoors on cold winter nights.

Persons using medications (particularly neuroleptic medications) that are likely to increase susceptibility to the cold should be advised by their physicians regarding their increased vulnerability to cold stress.

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*Deaths attributed to excessive cold (ICD code E901) were analyzed using mortality data tapes for 1976-85 from the National Center for Health Statistics.

State-Specific Estimates of Smoking-Attributable Mortality and Years of Potential Life Lost—United States, 1985

CIGARETTE smoking is the chief avoidable cause of death in the United States.¹ Although annual estimates of smoking-attributable mortality in the United States vary by method and data source, the estimates are uniformly large and range from a low of 270,000² to a high of 485,000.³ An estimated 320,515 deaths were attributable to smoking in 1984,⁴ representing approximately 16% of the total deaths in the United States for that year. Years of potential life lost (YPLL) have also been used to measure the impact of smoking-attributable disease.^{4,5}

In 1987, a computer software program (Smoking-Attributable Mortality, Morbidity, and Economic Cost (SAMMEC) developed by the Center for Nonsmoking and Health, Minnesota Department of Health was distributed by CDC to other states.⁶ This software facilitates calculations of smoking-attributable mortality, YPLL, and economic costs. Using the software, all 50 states and the District of Columbia completed these calculations for 1985.

For smoking-attributable deaths and YPLL, the smoking-attributable fractions (SAFs) for 21 smoking-related diseases among adults were calculated using weighted

relative risks estimated from four prospective studies on the health effects of smoking.^{2,4} In addition, risks for four pediatric diseases related to maternal smoking were included in the SAMMEC calculations.⁷ Age- and sex-specific mortality data for 1985 were obtained from each state's vital records system. Age- and sex-specific weighted smoking prevalence rates (CDC, unpublished data) were obtained from the 1985 Current Population Survey (supplement) of the U.S. Bureau of the Census. The smoking-attributable YPLL were calculated by two methods: 1) to age 65 years and 2) to average life expectancy.⁵ State-specific rates per 100,000 persons for smoking-attributable mortality and YPLL were calculated using state-specific population data provided by the U.S. Bureau of the Census for 1985 (U.S. Bureau of the Census, unpublished data). These rates were not age-adjusted because insufficient age-specific population data were available to permit it for all states.

According to state-specific estimates, more than 314,000 U.S. deaths were caused by smoking in 1985. The average number of smoking-attributable deaths per state was 6168 (ranging from 271 in Alaska to 28,533 in California). Of all smoking-attributable deaths in the

Table 1
SMOKING-ATTRIBUTABLE DEATHS AND YEARS OF
POTENTIAL LIFE LOST (YPLL), BY STATE—UNITED STATES, 1985

State	Smoking-attributable deaths	YPLL before age 65	YPLL before life expectancy	State	Smoking-attributable deaths	YPLL before age 65	YPLL before life expectancy
Alabama	5,174	19,131	44,956	Nebraska	2,231	4,595	22,016
Alaska	271	2,031	4,762	Nevada	1,474	4,869	19,125
Arizona	3,844	9,826	44,442	New Hampshire	1,398	3,549	15,620
Arkansas	3,845	11,357	45,265	New Jersey	10,180	30,723	75,888
California	28,533	79,491	331,415	New Mexico	1,217	3,956	14,245
Colorado	3,005	8,728	35,028	New York	26,880	78,176	335,319
Connecticut	4,269	11,366	48,470	North Carolina	8,297	34,772	112,805
Delaware	849	3,163	11,056	North Dakota	760	3,382	4,335
District of Columbia	911	4,185	12,736	Ohio	15,881	49,178	187,208
Florida	18,186	45,030	204,593	Oklahoma	4,731	13,586	54,999
Georgia	7,539	28,912	96,943	Oregon	3,737	8,618	41,803
Hawaii	766	2,987	12,554	Pennsylvania	17,961	46,658	207,325
Idaho	959	2,252	10,527	Rhode Island	1,571	3,494	17,254
Illinois	15,846	49,665	193,435	South Carolina	3,979	14,815	51,987
Indiana	7,945	23,063	94,012	South Dakota	963	2,245	10,133
Iowa	4,017	8,425	41,037	Tennessee	6,537	22,460	82,274
Kansas	3,153	7,762	34,229	Texas	16,828	57,007	208,946
Kentucky	6,497	20,782	80,039	Utah	742	3,371	12,343
Louisiana	5,571	18,421	71,361	Vermont	740	1,907	8,438
Maine	1,861	5,207	21,031	Virginia	7,184	24,693	92,115
Maryland	5,266	17,676	38,491	Washington	5,593	15,239	65,133
Massachusetts	8,515	20,653	90,422	West Virginia	3,325	8,531	38,573
Michigan	12,453	38,974	150,591	Wisconsin	5,636	13,583	59,816
Minnesota	5,039	12,304	53,476	Wyoming	497	1,828	6,056
Mississippi	3,233	11,285	40,634	Total	314,574	936,089	3,648,676
Missouri	7,638	19,410	81,418	Average	6,168	18,355	71,543
Montana	1,047	2,768	11,997				

United States, 67% were among men, 32% among women, and less than 1% among children less than 5 years of age. These deaths in young children resulted from low birthweight/short gestation, respiratory distress syndrome, other respiratory diseases of the newborn, and other diseases of children associated with maternal smoking.⁴ Smoking-attributable deaths accounted for approximately 936,000 YPLL before age 65 years in 1985. When average life expectancy was used as a cut-off point, approximately 3.6 million YPLL resulted from the smoking-attributable deaths.

The average state smoking-attributable mortality rate was 130.0 per 100,000 persons (ranging from 45.3 in Utah to 175.9 in Kentucky). The average rate of smoking-attributable YPLL before age 65 years was 447.8 per 100,000 persons less than 65 years of age (ranging from 223.5 in Utah to 773.6 in the District of Columbia). The average rate of smoking-attributable YPLL before actual life expectancy was 1503.8 per 100,000 persons (ranging from 643.2 in North Dakota to 2167.3 in Kentucky).

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CDC Editorial Note: Smoking causes more premature deaths than all other health-risk behaviors in the United States.⁸ The state-specific calculations of smoking-attributable mortality permit comparison of the impact of smoking with that of other health risks in states. Even as

Table 2
 SMOKING-ATTRIBUTABLE MORTALITY (SAM) RATE AND
 YEARS OF POTENTIAL LIFE LOST (YPLL) PER 100,000
 PERSONS, BY STATE—UNITED STATES, 1985

State	SAM	YPLL before age 65	YPLL before life expectancy	State	SAM	YPLL before age 65	YPLL before life expectancy
Alabama	129.5	545.2	1125.0	Nebraska	140.1	333.9	1328.9
Alaska	54.3	421.4	954.3	Nevada	158.5	582.4	2056.5
Arizona	122.6	313.3	1417.2	New Hampshire	140.6	404.7	1571.4
Arkansas	163.7	565.0	1927.0	New Jersey	134.9	466.4	1005.7
California	109.5	341.3	1272.0	New Mexico	84.9	305.7	994.1
Colorado	94.2	300.6	1098.4	New York	151.6	505.1	1890.6
Connecticut	135.0	413.6	1532.9	North Carolina	134.9	639.2	1834.5
Delaware	137.6	577.2	1791.9	North Dakota	112.8	577.1	643.2
District of Columbia	147.6	773.6	2064.2	Ohio	148.0	521.2	1744.7
Florida	161.3	485.7	1814.4	Oklahoma	144.1	472.2	1675.8
Georgia	127.7	544.5	1642.3	Oregon	139.1	369.2	1556.3
Hawaii	77.0	333.4	1261.7	Pennsylvania	151.6	459.6	1749.4
Idaho	96.1	253.3	1054.8	Rhode Island	163.6	425.6	1797.3
Illinois	137.8	490.3	1682.6	South Carolina	121.4	504.8	1585.9
Indiana	144.6	475.7	1711.5	South Dakota	137.2	371.7	1443.4
Iowa	139.5	341.4	1424.9	Tennessee	137.8	539.0	1734.6
Kansas	130.2	370.1	1413.3	Texas	103.6	387.8	1286.4
Kentucky	175.9	639.4	2167.3	Utah	45.3	223.5	753.5
Louisiana	125.1	459.3	1602.2	Vermont	138.3	404.0	1577.2
Maine	161.0	519.1	1819.3	Virginia	129.7	498.5	1662.7
Maryland	121.3	455.2	886.5	Washington	128.6	396.4	1497.7
Massachusetts	146.6	410.8	1556.3	West Virginia	171.7	508.4	1992.4
Michigan	137.3	483.9	1659.8	Wisconsin	118.1	326.7	1253.0
Minnesota	120.3	335.4	1276.9	Wyoming	98.4	394.0	1199.2
Mississippi	124.7	494.3	1567.1	Total	132.5	449.0	1539.3
Missouri	152.2	448.2	1622.8	Average	130.0	447.8	1503.8
Montana	127.4	382.3	1459.5				

smoking prevalence declines in this country,⁹ smoking-attributable illness will continue to produce an enormous disease burden well into the 21st century.¹⁰ Thus, efforts to reduce tobacco use in each state must continue to be a high public health priority.

The national estimate for the total number of smoking-attributable deaths reported here is remarkably similar to the 1984 estimate (320,515),⁴ despite the following differences in the methods used to calculate the two estimates: 1) the 1985 state-specific mortality data were used in these calculations rather than 1984 national mortality data; 2) different SAFs for lung cancer among women were used in the two calculations; and 3) deaths among nonsmokers caused by passive smoking (3825) and deaths from cigarette-caused fires (1570) were included in the previous estimate⁴ but not in the state-specific estimates used here.

The longitudinal studies used to derive relative risk estimates for the SAMMEC calculations involved persons who began smoking between 1900 and 1950. The pattern of smoking among U.S. men was well-established by the end of that period; however, women did not begin smoking in large numbers until the 1950s and 1960s.¹¹ Therefore, the results produced by SAMMEC probably underestimate the actual disease impact of smoking among women in 1985.

The smoking-attributable mortality and YPLL rates reported here were not age-adjusted, thus limiting comparisons among states. Despite these limitations, SAMMEC is a useful epidemiologic tool that helps organize and translate surveillance data into an understandable framework. Some states have already reported their use of the data produced by SAMMEC.¹²⁻¹⁴ The SAMMEC software also demonstrates the effectiveness of public health surveillance data when linked by state epidemiologists, state-based health promotion professionals, state vital records departments, federal public

health agencies, and others in addressing smoking and other problems.

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View from the Hill

JAMES E. BRYAN

IT would be difficult to exaggerate the timeliness—or to challenge the basic rationale—of the resource-based relative-value scale (RBRVS) study released September 29 by the study's project director, William C. Hsiao, Ph.D., of the Harvard School of Public Health, Boston. A number of distinguished colleagues have served with Dr. Hsiao in this impressive, congressionally mandated effort to develop a new and more equitable formula for reimbursing physician services rendered to Medicare patients.

With the assistance and encouragement of the Health Care Financing Administration, the Physician Review Commission, and many physicians and members of Congress, this report offers the prospect of bringing Medicare physician costs under a type of control totally different from, but equally effective as and (one must hope) eminently more acceptable to the profession than the DRG formula. The DRG device has been applied, with highly questionable satisfaction, to Medicare hospital charges since 1983. It is admittedly inapplicable and unadaptable to the reimbursement of physicians' services under Medicare.

The current levels of compensation for physician services ride on a movable base of usual, customary and reasonable (UCR) charges, a sort of vague tautology that offers both a comforting ring of flexibility and a tone of homey warmth and rationality. Whatever else may be said for it, UCR lends itself to outlandish inflation of charges and notable distortion of reimbursements for procedural services relative to those for cognitive services.

This report by Dr. Hsiao and his colleagues presents resource-based relative values (RBRVs) for selected procedures of four major specialties—family practice, internal medicine, general surgery, and thoracic and cardiovascular surgery. The program, as outlined in the "Special Report" published in *The New England Journal of Medicine*, September 29, compares fees and charges for typical services in the illustrative specialties, as calculated (in relative value point terms) with 1986 mean Medicare submitted charges. In each case, the total RBRV is shown as the sum of factors for intra-service work, pre- and post-service work, the opportunity cost of specialty

training, and the relative practice costs inherent to the specialty.

The investigators suggest that RBRVs "might well be quite different from charge-based relative values, producing fees that would differ from current charges and altering physicians' economic incentives." They note that, in consequence, "such a change in incentives might influence physicians' practice patterns, although how strong an influence it would exert is still unresolved and vigorously debated." The investigators suggest that "at least theoretically, total health care costs could be reduced by an alteration of physicians' practice patterns."

Predictably, applying the RBRVS fee schedule (denominated in nonmonetary units) to conversion factors (so many dollars per unit)—as would presumably be done eventually, using conversion factors to reach negotiated fee schedules in various areas—would result in quite different levels of remuneration for various specialists than obtained today among these groups. Speaking to this point in an accompanying "Sounding Board" statement, William L. Roper, M.D., HCFA spokesman, associates himself as a pediatrician and the Secretary of Health and Human Services, Otis Bowen, M.D., as a family physician in sharing the concern with the problem of "perceived inequities in [Medicare] payment across different specialties and services." He observes, "Many have suggested that surgical and diagnostic services have been relatively overpaid, and that cognitive or primary care services have been relatively underpaid." Dr. Roper warns against accepting the RBRVS as a "magic bullet," noting that "the critical problems of increasing volume and intensity would remain, as they would under any fee-for-service system."

Generally speaking, the committee's account of the manner in which it approached its charge, the imagination, care and industry it brought to an unprecedented pioneering enterprise is difficult to fault. The committee augmented its technical work with many formal consultations with physicians, third-party payers, consumers and health service researchers. A prestigious and broadly representative advisory committee was designated and, under its subcontract calling for support and assistance from the American Medical Association, consultation was extended among many physicians. More than 30 specialty societies each nominated three representatives, assuring adequate representation geographically as well

JAMES E. BRYAN, Washington Correspondent, *American Family Physician*.

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AROUND THE STATE

as between academic and clinical practices. RBRVs were developed for approximately 2,000 services, accounting for about 80 percent of Medicare payments to physicians in 14 specialties.

Under an RBRVS fee schedule, the most sharply affected specialties would be family practice, internal medicine, allergy, ophthalmology and thoracic surgery. "An average family physician could receive 60 to 70 percent more in revenues from the Medicare program. By contrast, the average ophthalmologist and thoracic and cardiovascular surgeon could receive 40 to 50 percent less," according to the committee. Such a schedule is projected to have "very little effect" on the revenues of physicians specializing in obstetrics and gynecology, orthopedics, otolaryngology, psychiatry or urology.

Finding no "gold standard" by which its work might be measured, the committee turned to a roughly comparable experience in Ontario. Since the early 1970s, Ontario's provincial fee schedules have been established through negotiation between the provincial government and the provincial medical society. After agreement is reached, the medical association brings together representatives of the various specialties to negotiate a uniform and equitable schedule among themselves.

The committee found, as a "general pattern," that "most evaluation and management services have lower ratios than do services in the other categories. In other words, relative to resource cost, these services are compensated at a lower rate than invasive, imaging and laboratory services ... at less than half the rate of invasive services." This applies whether the evaluation and management services are performed by surgeons, internists or family physicians. The committee also found that such services tend to be more adequately compensated in hospitals than in office settings.

The work of the Hsiao group responds to a public need to rationalize a substantial public beneficence. Just as water seeks its level, so public disbursements tend ultimately to relate themselves to the real costs of the private goods or services provided. The profession, I venture to suggest, would be well advised to accept with grace the growing public perception that "cognitive medicine" responds most directly to humanity's deeply felt needs. Hence, the long-standing imbalance between the profession's evaluation of procedural medicine on the one hand and evaluative-management services on the other is not only inherently unrealistic but increasingly rejected by the public. Equally pertinent here is the impending political review of Medicare health costs, in which medical charges historically offer a favorite target for budget balancers.

The stakes in the coming debate over the RBRVS are high: The issues involve the professional integrity and the public respect of American medicine. An early decision will be demanded both by political pressures and the public interest.

HCMA Shelter Clinic

While serving on the HCMA's Community Health Committee in 1985, James G. Patillo, III, M.D., learned that the medical needs of the area's homeless were not being addressed in city shelters. Recognizing that this population was at high risk for medical problems, Dr. Patillo and other committee members cleared a storage room in the South Park Inn emergency shelter. There, they set up an infirmary stocked with donations from hospitals and medical suppliers. Referral networks were coordinated with area hospital clinics and HCMA physicians volunteers.

The South Park Inn Medical Clinic (SPIMC) currently serves Hartford's homeless population under the advisement of the HCMA as a student-run program of the University of Connecticut School of Medicine. Approximately 70 medical students participate in the operation of the clinic, which is open every Tuesday evening. It is staffed by two fourth-year medical students functioning as primary care givers; two second-year students to take histories and assist in physical exams; and a first-year student, who performs clerical duties.

The students are supervised by physician preceptors, strengthening the quality of care and providing the doctor an opportunity for involvement in medical education and community service. Physicians serve on an advisory board comprising University of Connecticut professors, hospital, and HCMA representatives.

The clinic is seeking physicians to volunteer on Tuesday evenings from 6 to 8 p.m. on an alternating schedule, once every two to three months. According to Kathy Pae, second-year medical student and director of physician volunteers at the clinic, support from HCMA members may enable them to open an additional night each week. To volunteer at the South Park Inn Medical Clinic, call Ms. Pae at 724-0071.

HCMA Foundation Fund Drive

The Hartford County Medical Foundation's current annual fund drive has a goal this year of \$4,500.

Last year, 120 members contributed nearly \$3,600 for the Foundation's support to Charter Oak Terrace-Rice Heights Health Center, Community Health Services, the Medical Students' South Park Inn project, and the University of Connecticut dean's discretionary fund. In addition, the Samuel H. Cohn, MD memorial scholarship fund awarded a \$1,000 scholarship to William Webb, a fourth-year medical student at the University of Connecticut.

Construction Begins At Yale On Center For Molecular Medicine

—Yale University and its School of Medicine have begun construction of the Center for Molecular Medicine (CCM), a \$34.6 million facility for both basic and clinical research. The center, a collaborative project of the School of Medicine and the Howard Hughes Medical Institute in Bethesda, Maryland, is scheduled to be completed in the fall of 1990, and will take advantage of the scientific advancements of the past two decades, such as recombinant DNA technology, to accelerate the transfer of new discoveries from laboratories to patients. According to Dr. Leon E. Rosenberg, dean of the School of Medicine, "This project holds tremendous potential for medical progress at Yale. The center is one of the university's most significant investments in basic sciences research of this generation, and it will help to sustain Yale's reputation at the forefront of medical research."

Rules for Surviving a Chief Medical Residency

HENRY SCHNEIDERMAN, M.D.

ALTHOUGH unsought admonitions abound, the literature offers scant advice for the incoming chief medical resident (CMR), especially concerning the toughest parts of the job: efficiency and retaining sanity. The 13 maxims in this article attempt to fill this void. A few came from outgoing CMRs, some from other people, and some incorporate published insights on physicians' mental health.¹⁻⁷ All sit best on a pattern of constantly displayed energy, intelligence, and interpersonal skills.

- *Work on your life outside the hospital every day; cultivate your loved ones and your interests.* This requires topmost priority in order to command sufficient attention. Human relationships do not tolerate being put on hold; they grow with sustained work or they wither. Do not become the greatest chief resident ever at the expense of your marriage. Remember that an "understanding" spouse is a liability and, perhaps, a time bomb, whereas a demanding one is an asset. Friends, family, and especially your own children must have your attention, regardless of the pressures on you.

To keep your perspective on the chief residency, seek other kinds of personal development, too, whether reading detective stories, playing the cello, or writing to Congress. Physical exercise promotes mental well-being and combats stagnation. Like many other nonmedical activities, it can be shared with friends or family. Chief residency requires "people" skills rather than medical brilliance, and humanization serves the job best. You were a person long before you were a doctor, and you will be one long after the transitory chief residency ends. You should not lose yourself.

- *Spend part of each day on your own education and pleasure in medicine.* Being CMR does not serve every professional need. If you take no time for personal education, the realization that you labor for others' growth while no one fosters yours may embitter you. Medical treats during my year-long chief residency included establishing physical findings rounds with students, taking clinical photographs, and reviewing autopsy hearts for correlations. Possibilities are endless; most dovetail with teaching or administration, but that is not a criterion. Reserve one hour per working day for this, and not by prolonging the day.

- *Staying longer at the hospital means collecting more work to do; resist the urge.* Since work expands to fill time, the habit of completing tasks by some reasonable hour, such as 5:00 p.m., trims waste. Do not try to prove

your dedication by staying late, and stay away from the hospital on weekends, unless something specific demands your presence. Telephone calls at home should be limited to emergencies, because they let the hospital metastasize into the farthest recesses of your life. They destroy peace far beyond the actual time spent on the wire, since you struggle to resume whatever preceded the interruption. Appoint the seniormost in-house resident to handle such off-hours problems as transfers to the Intensive Care Unit or disputes between ward teams, with instructions to call you only for extraordinary situations. Unlimited availability and attendant weariness form the popular image of the "real doctor," and often our implicit one as well; but it is false and harmful. Equanimity serves better; you are more likely to come out swinging the next morning if you have really recuperated the night before.

- *If you are unhappy, consider that more work will seldom correct problems or make you feel better.* Recognize overwork and do not try to solve it by doing still more. In Rhoads' study of overwork,² the traditional physician response of "digging in" worsened the basic lesion, exhaustion, and thus lowered efficiency; one tries harder and harder and falls farther behind. Rest, diversion, departure, even (heaven forbid!) a mental health day are not signs of moral degeneracy, but rather rational responses. Not every low feeling in the chief residency represents overwork, but unrecognized overwork always should be considered.

- *What else helps to avoid overwork? Learning to say No more often.* CMRs must combat their deficiency of leukocyte negativity synthetase. If a request is reasonable and comes from someone who has been supportive, and if the chore is vital, and if it really calls for you, consider saying Yes. Otherwise, say No. Refusals are easier when you offer an alternative: "Could Dr. Jones do this?" However, never make the alternative the basis for refusal, or you will be scooped: "I already asked her," or worse, "I don't like her." Preface refusal with something you control, such as "I'm too swamped this month." Even the old adage "My chairman said ..." may threaten an old bull's sense of clout and catch you in the cross fire. Beware of seduction. "You're the best bedside teacher" usually heralds an improper request.

- *In addition to limiting work intake, survival requires that you plan your time carefully.* Chief residency is rife with interruptions, and if you let chaos rule, it will. Distinction between the most important tasks and the most pressing is not always clear; leading questions may assist, such as "Who suffers if this isn't done?" or "Will this matter six months hence?" Do not disregard your schedule, because intrusions and crises are inevitable. If you make lists divided into columns labeled *Now*, *Today*,

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and *This week*, do not overload the *Now* column with tasks that are not urgent. Assign time limits to open-ended activities, such as medical student teaching, and adhere to them rigidly, or days will be gobbled up. Increase use of support people. When materials or arrangements are needed on short notice, you frequently do them yourself by default, which wastes time and energy.

Establishing a list of priorities involves recognizing that there are always too many tasks. A CMR's time and energy are not infinite, and some plans, needs, and even persons cannot be addressed. The hospital and the program will never be perfect. To attack every loose end is akin to a sprint in the middle of a marathon. Letting go of tasks selectively, not randomly via exhaustion, requires ridding yourself of a swollen self-image and guilt associated with not being all things to all people.

- *Another key to avoiding burnout is to delegate responsibility; do not try to do it all yourself.* Even if it takes longer to teach another than to do the task yourself, benefits include greater involvement of the resident, nurse, or secretary, a greater sense of shared goals, diminished reliance of the system on yourself, and a reputation for not being the path of least resistance. Sometimes the problem is not to complete the task, but to find a mechanism that avoids being a workhorse. You do not have to prove yourself by doing everything. Some general medicine consultations can go to the ward resident with the smallest service; scheduling, to a secretary or, perhaps, a machine; and responsibility for remedies, to those who created the problem.

- *Know the difference between your problems and others'.* If you solve someone else's problem, you guarantee an endless succession of parallel cases. Your duty is to explicate the situation and then to advise steps. If an intern says, "I have to change January call," one fit answer is, "Leslie, you do have a problem, and this is what *you* need to do to solve it." Based on a background of credibility and support, this response communicates a positive message about competence, rather than a putoff. A colleague once said, "Your job is to give ulcers, not to get one"; this hyperbole underscores that you cannot afford to shield trainees from too much stress when it means taking extra stress upon yourself. The CMR job description is to be a leader, not a martyr. If a resident is inundated with admissions, the CMR should not start doing workups; he should telephone the backup resident or even a protesting off-service resident for assistance.

- *If house staff complain about such steps, you may have to remind them that chief residency is not a democracy, nor a popularity contest.* You should not bargain for house staff approval. This looms largest when the CMR is a third-year resident and feels he must appease former peers who are now subordinates. You cannot please everybody and should not waste time trying. If you avoid caprice and autocracy, propriety and decency will speak for themselves.

- *Do not apologize.* When there is a conflict, an apology is often a false solution that implies culpability and is

suitable only after wrongdoing. Apology can become a habit, and a demeaning one. Admit errors readily; anything less undercuts you.

Beware of toxic personalities who twist an apology into an excuse for their own passive-aggressive behavior. They have no right to do so, for we all serve patient care. Wealth, power, publications, and fame are incidentals, possible only because society charges our profession with care of the sick.

- *Loyalty to patients outweighs loyalty to house staff, department, or institution.* This does not excuse self-righteousness, the ugliest form of self-indulgence. Such priority deserves enunciation, both at house officer orientation and when a conflict of interests is identified. Loyalty to patients implies attending to the mental health of the house staff, and to their program, since happy, well-rested house officers provide optimal care.

- *However, speak up whenever standards are failed, despite the universal tendency to avoid unpleasantness.* If patients have been mistreated or responsibilities ignored, the medical analogy is the sore that festers rather than heals. Verbal discussion of failings is vital. Confrontation must proceed with tact, an open mind for both facts and interpretation, and an ability to emphasize the positive. A dispassionate style helps, as well as a statement that everybody errs, including you. When a trainee repeatedly strays, written notice provides necessary documentation; a carbon copy to the program director is a more overt threat. If concern for the feelings of the violator silences you, you may find yourself telling the recalcitrant offender, "Martin, that's the sixth time you've left the hospital without signing out," to which Martin will reply, "I always signed out. And no one ever had a problem with me before." Consistency, openness, and constructive criticism allay the policeman image.

- *In summary, do not burn yourself out.* Impatience and enthusiasm contribute to a CMR's effectiveness, but only if they do not run wild. Keep some reserve for the next drastic crisis. Acknowledge mistakes without feeling that they must all be undone immediately. Do not take work home, and stay home when you are sick. The program stumbled along without your guidance last year, and it will again. Be as lenient with yourself as you are with your house staff or, better yet, your patients.

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Cost-Containment and Medical Malpractice

JULIUS LANDWIRTH, M.D., J.D.

“WHILE we recognize, realistically, that cost-consciousness has become a permanent feature of the health care system, it is essential that cost limitation programs not be permitted to corrupt medical judgment.” So wrote Judge J. Rowen of the California Court of Appeals in deciding the nation’s first case to test the issue of liability for patient injury resulting from decisions by physicians and third-party payors to restrict clinical services.¹

Much has been written about the effects of changes in the organization and reimbursement mechanisms for the delivery of health care services on the traditional physician-patient relationship.²⁻⁴ The ethical and legal duties that derive from that relationship require that the physician utilize all available resources for the benefit of his patient. That duty conflicts with cost-containment strategies, especially prospective payment systems, that create incentives to curtail utilization. Nevertheless, the patient who is injured when care that should have been provided is not provided will probably recover damages from someone. Mrs. Lois Wickline was such a patient who brought suit against a third-party payor. In deciding that case, the California court began the process of defining the respective legal positions of providers, patients, and payors in that increasingly complex enterprise we know as “providing patient care.”

Facts of the Case

Mrs. Lois Wickline was, in 1974, a 45-year-old former model and beautician, mother of four, and sole supporter of her family since her husband had been invalidated by injury and cardiac problems. That year she began experiencing back pain and some pain in her legs on walking. Her general practitioner physician, in consultation with a surgeon, diagnosed peripheral vascular disease. When, after a period of conservative management, her symptoms persisted, an operation was recommended. Preauthorization for a ten-day hospital stay was requested and granted by MediCal. She was admitted to a community hospital where a peripheral vascular surgeon performed

a bilateral aortofemoral bypass graft.

Within a few hours after surgery had been completed a clot developed in the right femoral artery requiring a thrombectomy. She subsequently continued to have intermittent vascular spasm and marginally acceptable peripheral circulation. As the end of her authorized length of stay approached, her physicians felt that an additional eight days of hospitalization was indicated. Following the prescribed procedure, an application for an extension of hospital stay was completed and submitted to MediCal. The MediCal procedure was for the application to be reviewed by a Health Care Service Nurse based at a regional office. The nurse was authorized to approve requests but not to deny or authorize a lesser number of days than requested without first contacting a MediCal physician consultant.

Upon review of the application, the MediCal nurse questioned the necessity for additional stay based on the information provided in the form. She therefore contacted a MediCal physician who reviewed the information on the form and authorized an additional four days.

At the end of that time, Mrs. Wickline was discharged from the hospital. During the subsequent ten days she experienced progressively increasing pain in her legs. When seen again by her surgeon she had obvious signs of progressive vascular insufficiency and infection at the surgical site. She was admitted on an emergency basis but her condition worsened and amputation of her right leg ultimately was required.

The Court’s Decision

She retained a local law firm and filed a claim against the State of California for careless and negligent abandonment while she was in need of continuing hospital care. (Interestingly, she refused to sue her physicians with whom she had excellent rapport.) She contended that had she remained in the hospital her complications would have been detected earlier and the amputation avoided. She also claimed that the MediCal nurse and physician consultant were negligent in never having talked with her or her physician nor having reviewed her medical record. Both sides agreed that the attending physician is generally in the best position to know what the patient’s needs are. However, the attending surgeon,

JULIUS LANDWIRTH, M.D., J.D., Director, Department of Pediatrics and Advisor for Medical-Legal Affairs, Hartford Hospital, Hartford, CT.

who testified that her condition on discharge was stable, although worrisome, also stated that he did not persist with further appeal of the decision because he felt that MediCal had the power to tell him when to discharge a patient. In a magazine interview, one of the physicians was later quoted as saying "This wasn't the first time that had happened. I've had patients who couldn't walk, and the MediCal people have said 'He's got to get out.' I've said, 'Please, at least see him,' but they wouldn't even do that."⁵

The State argued that the discharge order written by the physicians indicated that they saw no compelling reason to keep her in the hospital.

In his instructions to the jury, the judge stressed that the MediCal consultant was required to review the medical information and determine if an eight-day extension of stay was necessary according to the usual standard of medical practice in the community. After only four hours of deliberation the jury reached a decision in favor of Mrs. Wickline and awarded her \$500,000.

The case was appealed in 1986, the State claiming it was not negligent as a matter of law. The State argued that the physicians discharged the patient based upon the prevailing standard of care and that MediCal took no part in the decision.

Furthermore, the State argued that the standard of due care to be followed by the MediCal physician Consultant is to make decisions based on the information provided on the official form and not to solicit further information from the medical record, the attending physician, or the patient. The Appellate Court reversed the lower court's finding in this case with the following explanation:

"Third party payors of health care services can be held legally accountable when medically inappropriate decisions result from defects in the design or implementation of cost-containment mechanisms, as for example, when appeals made on a patient's behalf for medical or hospital care are arbitrarily ignored or unreasonably disregarded or overridden. However, the physician who complied without protest to the limitations imposed by a third party payor when his medical judgement dictates otherwise cannot avoid his ultimate responsibility for his patient's care. He cannot point to the health care payor as the liability scapegoat when the consequences of his own determinative medical decision go sour. There is little doubt that Dr. Polansky was intimidated by the MediCal program, but he was not paralyzed...nor rendered powerless to act appropriately if other action was required under the circumstances....This court appreciates that what is at issue here is the effect of cost-containment programs upon the professional judgement of physicians to provide hospital treatment to patients requiring the same. While we recognize realistically that cost-consciousness has become a permanent feature of the health care system, it is essential that cost-limitation

programs not be permitted to corrupt medical judgement. We have concluded from the facts an issue here that in this case it did not."

Discussion

The California Court has set the stage for analysis of future cases by establishing that third-party payors as well as physicians may be held liable for negligence. As new cases arise, the traditional elements of negligent malpractice claims may require reinterpretation in the context of changed provider-patient and third-party-payor settings.

There is little to suggest any shift in the physician's legal and fiduciary duty to act in the best interests of his patient by utilizing all available resources according to accepted medical standards. Increasingly, national medical standards, rather than local customs, have been adopted as the legal test.⁶ These standards include no provisions for consideration of nonmedical factors, such as service restrictions imposed by third party-payors. However, as the influence of nationally pervasive cost-containment strategies effects patterns of practice, standards of care may evolve that will reflect the realities of resource limitations. Traditional notions of a unitary medical standard of care may then be replaced by resource-based classifications, with particularly onerous consequences for the poor.

An aspect of due care suggested by the court concerns the appropriate response by a physician to a denial of preauthorizations of services by the third-party payor. How exhaustive must an appeal on behalf of the patient be to insulate the physician from liability? What are the physician's duties to the patient when a vigorous appeal is rejected?

According to the California court, third-party payors may be held liable when requests for services are "arbitrarily ignored" or "unreasonably disregarded or overridden." Public policy favoring cost-containment may encourage future courts to define "arbitrariness" and "unreasonableness" narrowly, requiring evidence of gross negligence or recklessness in the design and implementation of the process for reviewing requests and appeals before finding payor liability.⁷

A related issue not explicitly discussed in the case is the matter of informed consent. The fiduciary relationship created between physician and patient is the basis for the ethical and legal principles underlying the informed consent doctrine. The modern view requires disclosure of information that a reasonable patient would consider material to arriving at an informed decision about medical care, including risks and alternatives.⁸ Applying this "materiality" test may require discussions with patients about the range of available options based on services their payor will preauthorize, the associated risks and alternatives, the physician's best medical judgement according to accepted standards of care, and any financial interest the physician may have that might be adverse to the patient.

Potential hospital liability was another area not addressed in this case. Cost-containment strategies, prospective payment systems and contracts with third-party payors create powerful incentives for hospitals to constrain resource utilization. At the same time, it has been recognized that hospitals have independent duties of care to patients.⁹ Although not a party in the Wickline case, one can envision situations in which shared physician-hospital liability might apply.

The law moves relatively slowly compared to the rapidly changing environment in which medicine is practiced. Long-standing legal principles may fit awkwardly with new health care formats. Although some commentators have proposed that under certain circumstances cost-containment factors be accepted as a malpractice defense,¹⁰ prevailing legal principles do not permit balancing of conflicts between financial considerations and good patient care.

In an *amicus curiae* brief filed in the *Wickline* case, the California Medical Association expressed concern that "physicians not be placed between the proverbial rock and hard place. If the third-party payor imposing these controls is permitted to avoid liability by maintaining the fiction that the mechanisms have only fiscal consequences, so that patient care is solely the physician's responsibility, the physician becomes the insurer. If rationing malfunctions, the physician who complies with the pro-

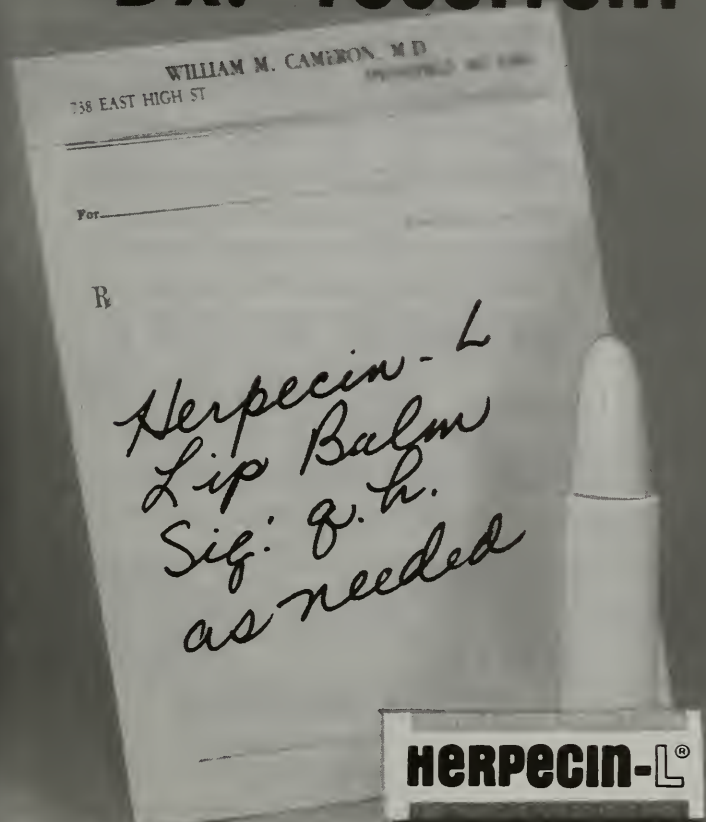
gram is liable to the patient. If the physician does not comply, the physician is punished or faces responsibility for incurring unauthorized costs."¹¹

The result in the Wickline case, while alerting payors to their potential liability, has not made the physician's position any less precarious.

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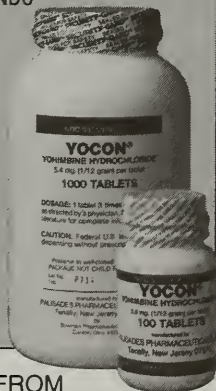
Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.^{1,3,4} 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to 1/2 tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.³

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CSMS-1988: The Society's Year in Review

ROBERT J. BRUNELL

CMIC, the physician-owned and directed professional liability insurance company founded by CSMS in 1984, ended its fourth account year with invested assets of \$90 million, and 2,400 members.

- Following a meeting with the Connecticut Insurance Department, M.D. Enterprises of Connecticut (MDEC) has completed capitalization arrangements to maintain the Department's \$1 million reserve requirement for HMO's, while providing sufficient capital to bring M.D. Health Plan to breakeven. The MDEC arrangements include funds raised from the Company's second stock offering completed on 12-31-88, as well as from CSMS-IPA, Inc. MDEC is the 100% physician-owned holding company founded by CSMS in 1987.

- M.D. Health Plan begins 1989 with 12,000 HMO enrollees. In addition, MDEC's innovative, employer-funded joint venture with Stirling and Stirling, Inc. now has some 4000 enrollees. These combined programs, it is anticipated, will generate in excess of 100,000 patient visits and \$12 million in physician fees in 1989 for CSMS-IPA members.

- A prominent plaintiff's attorney has paid \$99,000 to a Waterbury cardiologist in settlement of the physician's countersuit against him alleging that earlier litigation against the doctor, withdrawn after weeks of trial and adverse publicity, was groundless.

- The Connecticut Supreme Court handed CSMS a victory over incursions into the practice of medicine by limited-license practitioners, by rejecting podiatry's definition of "foot" as including the ankle.

- The CSMS Medicare Courtesy Card, although highly successful as a voluntary Society program and widely imitated in other states, became a mandatory state program in the final minutes of the 1988 session of the state legislature. Its \$19,500/\$24,000 income limits, however, were retained intact, thus keeping the program based on need. This was of some consolation, at least, given the political feeding frenzy in process as the clock approached midnight of the final day of the election-year session.

- Connecticut's AMA Delegation grew again, to five CSMS delegates and five alternates, thanks to still increasing AMA membership among the physicians in our state. CSMS membership also reached a new high.

- CHIS, the new CSMS-sponsored buying service for physicians, added medical waste disposal to its growing list of supplies and services provided at volume discounts.

- Another new CSMS membership benefit, the Dodson

Workman's Compensation Insurance Program, began offering coverage this year, featuring a remarkable and substantial annual dividend program based on favorable experience.

- The new CSMS Hospital Medical Staff Section, representing some thirty-two hospital medical staffs, held its first Annual Meeting in the spring, and its bylaws were approved by the Society's House of Delegates in the fall. CSMS-HMSS was represented by its president at the national AMA-HMSS meeting in December.

- A photography contractor is now at work taking portraits of all CSMS members, so that the Society's 1989-90 "Medical Directory of Connecticut" will be a *pictorial* directory. It has become the major referral source in our state, and is a real benefit to CSMS members.

- The CSMS Physician Health protocol was signed by Society and State Department of Health Services officials this year, to service the needs of physicians in the five small county medical associations. The larger Fairfield, Hartford, and New Haven county associations already have their own state-approved impaired physician programs in operation.

- The Council has authorized the appointment of a special CSMS Bicentennial Committee to plan the observance of the Society's 200th anniversary in 1992. A copy of a 1942 CSMS historical publication, *The Heritage of Connecticut Medicine*, is being sought. Hardbound in red cloth, it was published in observance of the Society's sesquicentennial anniversary.

ROBERT J. BRUNELL, M.A., Director of Scientific Activities, Connecticut State Medical Society.

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Reye's Syndrome

The paper by Eagel et al in this issue of *Connecticut Medicine*¹ reports an additional case of Reye's syndrome in an adult. This syndrome, first described by Reye et al² in 1963, has been reported from time to time in adults since at least 1979.³ The oldest individual reported with Reye's was 59 years old, and 20 more cases have been reported in individuals age 16 and above. While there has been an overall decline in the incidence of Reye's syndrome from 0.47 cases per 100,000 in 1981 to 0.16 per 100,000 in 1986, most of the decrease has occurred among individuals less than ten years of age. The reasons for this decline are unclear but have been attributed in part to reduction in aspirin use.⁴ In 1986, 38% of patients with Reye's syndrome were under 4 years of age, 12% 5 to 9 years, 34% 10 to 14 years, 15% 15 to 19 years, and only 2% older than 20 years.⁵

With the increasing earlier recognition of this syndrome, and with improved treatment, the fatality rate has dropped from 41% in 1974 to 27% as of 1986.⁵ During the period of time that Reye's syndrome has been observed there has been a demonstrated close association with three prodromal viral illnesses: influenzas A or B, or primary varicella virus infection. Less frequently the syndrome has been associated with other viruses (reovirus, Coxsackie virus, echovirus, parainfluenza, polio, and adenovirus) or premonitory syndromes (acute respiratory or gastrointestinal illness).

A variety of other epidemiologic factors has been noticed since Reye's syndrome was first described.⁶ These include the possibility of a genetic predisposition to the syndrome in that Reye's seems to occur occasionally among siblings. Also toxins such as allantoin, aflatoxin, pesticides, and environmental pollutants have been considered as potential contributing causal factors. It is an interesting fact that Reye's syndrome has now been convincingly demonstrated to be more frequent among individuals who have used salicylates. In a study of Reye's syndrome among patients who were matched with classmates who had experienced similar antecedent respiratory illnesses, patients and controls were similar except for the fact that patients more frequently had fever and had used salicylates.

Mitochondrial injury has been noted to be a substantial factor in Reye's syndrome and elevations of aspartate and alanine aminotransferase have been noted to be

characteristic of the syndrome. Abnormalities have been noted in the urea cycle, and hyperammonemia in Reye's syndrome apparently results from the fact that ornithine transcarbamylase is reduced making it difficult to detoxify ammonia load.^{7,8} More recently medium chain acyl-CoA dehydrogenase has been noted to be decreased in asymptomatic siblings of children dying of both sudden infant death syndrome and a Reye's-like syndrome. The later finding introduces the possibility that some individuals presenting with Reye's syndrome might have an enzymatic deficiency that could be treated if it were recognized in advance.

It is possible that patients with Reye's syndrome may have impaired pathways for metabolizing salicylates.⁹ A variety of metabolic disorders have been suggested as etiologic factors, and there are a number of syndromes that can simulate Reye's syndrome including salicylism, propionic aciduria, methylmalonic aciduria, systemic carnitine deficiency, and hydroxymethylglutaric aciduria.

The Center for Disease Control definition for Reye's syndrome specifies: 1. An acute noninflammatory encephalopathy documented by alteration in the level of consciousness with the cerebrospinal fluid containing eight or fewer leukocytes per mm³ or histologic sections of the brain demonstrating cerebral edema without perivascular meningeal inflammation; 2. Hepatic disease documented by biopsy or autopsy, or by a threefold or greater rise in levels of either serum glutamic oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT), or serum ammonia; 3. No other reasonable explanation for cerebral or hepatic abnormalities.

The present report by Eagel et al on Reye's syndrome in an adult is of importance in that it stimulates interest and discussion about Reye's syndrome in individuals beyond the younger pediatric age groups where the syndrome was first noticed. As more and more cases are reported it is clear that the syndrome can occur in older individuals. Moreover it is clear that there is a tremendous problem with overlap between this syndrome and a variety of other metabolic syndromes that can simulate Reye's syndrome. Much work needs to be done to demonstrate potential underlying metabolic abnormalities in individuals who are identified as having Reye's syndrome. Some of these are well known metabolic disorders; others are not. The exact relationship of Reye's to various documented metabolic conditions remains unclear. As yet there has been no convincing demonstration of a single metabolic disorder consistently present in this disorder.

With respect to the present case report by Eagel et al, it should be emphasized that Reye's syndrome is a diagno-

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sis of exclusion: one has to suspect other disorders first. Significant factors relative to liver disease include the acetaminophen ingestion, the use of chlorpromazine in the past, as well as the use of salicylates. All of these agents can cause liver pathology and complicate our understanding of this report. The Center for Disease Control definition of Reye's is most adequate during times of peak influenza activity. At other times this simple definition is problematic. In a recent discussion with Dr. Eugene S. Hurwitz¹⁰ at the Center for Disease Control, Dr. Hurwitz emphasized that in reports of Reye's syndrome there is an increasing need to exclude the various metabolic diseases which can simulate Reye's. Furthermore, he emphasized that at this time he considers light microscopy no longer fully satisfactory to delineate Reye's syndrome and that electron microscopy should be performed if at all possible to confirm Reye's. Reye's remains a complex and enigmatic syndrome where some of the pieces have been identified (exposure to a virus and aspirin), but where other pieces remain to be found (the possibility of an underlying metabolic abnormality) before this reaction pattern can be thoroughly understood.

David P. Johnson, M.D.

Middletown, CT

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Letter to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

LETTERS OF REFERENCE AND HOSPITAL APPOINTMENTS

To the Editor: As the physician consultant to the Division of Hospital and Medical Care in the Department of Health Services of the State of Connecticut, I regularly visit hospitals in Connecticut as part of a licensure team. My recent (the past three years) focus has been the processes of review of appointment and reappointment processes for members of the medical staff. I am writing to alert your readers to a type of letter of reference that I have recently seen. It is unacceptable insofar as it does not allow the governing body of any hospital to exercise a meaningful, rational control of the privileges of its medical staff. The relevant section of the Public Health Code is Sec. 19-13-D3 (c) (1) (A).

I am enclosing, verbatim, the letters. I have removed identifiers although I saw the originals and they were from two different Connecticut physicians in two different Connecticut hospitals. They were part of the appointment folder of a physician applying to the staff of yet another, ie, third, Connecticut hospital.

Letter 1

"....This letter is in reference to your request for information regarding Dr. ——. Dr. —— worked as an emergency physician on a part-time basis from January 198- until August 198-. Officially, his privileges were temporary staff in the Department of [Emergency Medicine]. There were no grievances or complaints filed with any medical staff committee or other body of the institution during his time at —— Hospital. Dr. —— performed well as a member of the Department of [Emergency Medicine] during this time. He requested that his privileges be discontinued because of his other professional commitments.

We appreciated his service to the hospital.

Please do not hesitate to contact me if I can be of any further assistance.

"....In response to your letter of —— 198- regarding the affiliation of Dr. —— was appointed part time emergency room physician on —— 198- by the [Governing Body] of —— Hospital. He resigned

in the middle of 198-. Dr. ——— still has temporary privileges here, but has not been actively employed here for a year.

There were no complaints or grievances filed against Dr. ——— or any complaints relating to his competency, nor any restrictions of his license or privileges, while at ——— Hospital. While affiliated here, we have no knowledge of any privileges at any other health institution.

I trust this will assist you in the credentialing of Dr. ———. If I may be of further assistance, please do not hesitate to contact me.”

A letter of this nature is unacceptable in fulfilling the role of a letter of reference for two reasons. First of all, it does not allow any governing body to control privileges unless it appoints Dr. X but then grants him no privileges! There is no information about Dr. X's particular skills, limitations, character, or performance while at these hospitals (other than the blanket statement that he performed “well” in letter 1). Secondly, this type of letter would, if the other letters of reference were identical, cause the hospital to be in violation of its own medical staff bylaws in every one of the 41 hospitals I've visited over the past three years. This is so since every hospital's medical staff bylaws has a paragraph describing qualifications for membership. In this descriptive *and normative* section the usual stipulations refer to “good reputation, demonstrated competence,” etc. Letters like the ones above address none of these qualifications and raise the very real question whether the hospital's governing body can fulfill its obligation — given such a paucity of data — of controlling privileges in a meaningful way.

These letters are relatively worthless. They merely attest to the absence of deleterious information about Dr. X. As important as that information is, that could have been said in one sentence, thereby avoiding the self-protective format of such empty letters. If what one wants is merely the affirmation of “no grievances” etc., one can get this information from an administrator. What one wants from a medical peer is medical information, ie, the applicant's skills, weaknesses, interpersonal relations, etc. Ideally, the author of a letter of reference should address those privileges being requested at the applicant's hospital; however, this information is, unfortunately, often not provided the author.

Additionally, for whatever reason(s) the authors of these letters made them so scanty, they damn the applicant with their faint praise. Any credentials committee member who sees such a letter ought immediately to entertain at least two thoughts — either the author hasn't the *skill* to write a worthwhile letter of reference, or the author hasn't the *inclination* to write one since there is not much to say or, worse, there is something to hide. If the hospital requires three letters of reference and receives two like these, it needs two more of the worthwhile type. These count for very little.

I urge hospitals and physicians alike to consider the letter of reference an indispensable part of the processes of granting of appointments and privileges. Such letters need to be honest, as fair as possible to all the parties, and complete. Most of all, they need to be complete. Omitting important information is, at its best, not helpful. At its worst it is dishonest.

Richard M. Ratzan, M.D.

University of Connecticut Health Center
Farmington, CT

CALL TO ARMS

To the Editor: Now is the time for action. The new President will face tough choices when he is forced to deal with Medicare, long-term care coverage, mandatory assignment, uninsured employees and related consumer-driven health issues. No one, however, is at greater risk from these decisions than we physicians are.

We will bear the result of any manipulation of the system and its subsequent impact, direct or indirect, on the high quality of care we strive to deliver. If we do not now, each of us, take a more active role as informed citizens, our fate will be decided for us. Experts are now predicting that the next eight years will shape the face of medicine in this country for the coming three decades.

Physicians must not believe gullibly that one or two of us active in the “political” side of medicine will be enough. All of us must speak out. Politics is now creeping not only into reimbursement issues, but into quality of care concerns, limitations of hospital access, choice of physicians, and drug prescribing practices.

Many of the policymakers in the new administration will be lawyers with financial management backgrounds. They cannot rightfully be blamed for developing policy decisions that seem irrational to us physicians, if those with medical expertise have failed to assist, or even to challenge them. As a physician, you are a far better patient advocate than they or anyone else.

Please don't wait for an engraved invitation, either. Government leaders need to hear what you have to say when it counts. Don't think that the AMA or your State Medical Society lobbyists can “take care of the problem” without your active participation and support. Their calls for action need a prompt response from you.

Do write to your elected leaders politely and succinctly, with your ideas and possible solutions, not just complaints. Offer to serve as “informal” advisors to policymakers in your state and in Washington. Volunteer to speak to senior citizen groups, including AARP, on the

physician view of current health care controversies, and work together with seniors on issues where common ground can be established. Get involved and give your input to medical society committees that deal with these issues.

Perhaps our public image would improve dramatically if we were seen sacrificing some of our own limited free time to become more involved in helping formulate logical health care policies to benefit our patients. The "politicization" of medical care will continue in this country with or without our involvement. At least we could help write some of the rules we will be expected to obey.

Andrew D. Weinberg, M.D.

Branford, CT

BOOK REVIEW

Diagnostic Nuclear Medicine.

2nd Edition. Editors: A. Gottschalk, P.B. Hoffer, E.J. Potchen. Williams & Wilkins. Baltimore. 1988. xli + 537 pages + 28 page index in volume 1; xxiii + 617 pages + repeat index in volume 2, \$215.00.

That nuclear medicine remains a useful modality in medical diagnosis, even after the advent of both computed tomography and magnetic resonance imaging, is a fact borne out by the appearance of the second edition of this portion of Golden's *Diagnostic Radiology*. However, the change in the content of nuclear medicine's contributions is best shown by the wise decision to eliminate the chapter on speculating on the future that appeared in edition one. The passage of 12 years has been marked by the decline of the "brain scan" that depended upon leakage across the blood brain barrier, while entirely new areas have evolved, such as applications in cardiology and the advent of neuroreceptor imaging.

Seventy-five chapters cover nearly all of the diagnostic areas of nuclear medicine, as well as a few therapeutic applications (as in hyperthyroidism and thyroid carcinoma). There are approximately 125 contributors to these two volumes (and hence this reviewer's small chapter should not produce a conflict in an objective evaluation). Initial chapters cover the history of nuclear medicine, decision making, physics and instrumentation, and radiopharmaceuticals plus radiation dosimetry. The clinical chapters lead off with the cardiovascular system. Indeed, this is the largest section (about 296 pages in 16 separate chapters). Other large sections deal with neurology (156 pages), gastroenterology (150 pages), and bone (66 pages plus 19 on bone-marrow imaging in the

section on hematology). Some chapters have applicability in several sections. For example, a discussion of receptor-site imaging (chapter 54) is placed in the section on endocrinology; there are multiple applications to central nervous system imaging.

Monoclonal antibodies are mentioned on several pages, but there is no clear discussion of bone densitometry (either radionuclide or X-ray source of the beam). With the word "Diagnostic ..." in the title of the volumes, it is perhaps understandable that more was not done with other therapeutic uses of internally-administered radiopharmaceuticals. Pediatric aspects are covered in chapter 24 (cardiovascular) and chapter 66 (specific problems in children), with multiple references in other sections. Positron emission tomography is discussed in three principal sections; again there are references to the technique scattered throughout other chapters.

These are handsome and substantial volumes which stand as the next step in the evolution of nuclear medicine (the three-volume text on nuclear medicine edited by Freeman and Johnson had appeared in 1984-86). There are contributions by a good cross section of the nuclear medicine community (physicists, radiopharmacists, technologists, and physicians in specialty areas as well as those in nuclear medicine). Typographical errors appear few in number (on the contents page chapter 1 starts on page 1, not page 3 as stated, and Lang should be Lange).

For the expert in the field, or the physician who makes frequent referrals to nuclear medicine, these two volumes will stand as a useful guide to the present state of the field (and a reference point for following the advances of the specialty).

Richard P. Spencer, M.D., Ph.D

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NOTICE TO CONTRIBUTORS

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Please send them to:

Robert U. Massey, M.D., Editor
Connecticut Medicine
160 St. Ronan Street
New Haven, Connecticut 06511
(203) 865-0587

The President's Page

The 1989 Legislature and Us



By the time you read this, the 1989 Connecticut State Legislature will have convened what promises to be a trying session for organized medicine. We have prepared with a legislative forum held in October, and a well-attended dinner for county association and specialty section presidents in November. These programs have turned up a group of activist physicians who can address issues which need support at the Capitol.

The potential number of problem issues is awesome and still grows weekly. I've been called to be on a panel discussing universal health care, and the papers phone for my comments on whether chiropractors should or should not be allowed hospital privileges. Dr. Roger Beck, your CSMS President-Elect, has been present at many task force meetings attempting to resolve the nurse prescriptive authority issue, and a similar issue for physician's assistants waits in the wings. Our old friends—tort reform, Medicare assignment, triplicate prescriptions and direct patient access to physical therapists—will not go away. Whatever energy is left is devoted to positive issues—toxic waste control, tobacco and alcohol related bills, a nuclear freeze, state supported fitness programs. There are others I haven't named, and surely some not yet recognized as issues.

The make-up of the state legislature has changed little. As a whole it has followed the federal lead in reviewing medicine as a business rather than as a profession. Economic issues take precedence so that arguments for controlling health care costs are stronger than those which point out a declining standard of health care in Connecticut. I feel we must make it very clear to the legislature that passage of many of the bills being considered would lead to a lower level of care for the patients.

Even the noun denoting the person we are caring for has lost a nuance of professionalism and has been replaced by one connoting a business relationship. The dictionary defines *patient* as "one under medical treatment" and *client* as "one for whom professional services are being rendered." While the latter is formally correct, it gives a sterile and unfriendly ring to the relationship in my view. I believe this attitude underlies much of our present inability to convince legislators of the physician's special status as the patient's prime advocate, with our certified and long training at the medical school and postgraduate level. Giving any increased patient responsibility to limited license or unlicensed practitioners without showing additional and equivalent certified medical training is a *decrease* in the overall quality of health care in Connecticut.

Resisting these legislative pressures is not taking anything away from those non-MD's who want hospital privileges or direct access to patients, or prescriptive privileges, when they didn't have such responsibilities in the past, or any increase in certifiable *medical* training to warrant the change. Giving non-medical personnel those responsibilities would also add a layer of cost to an already overburdened health care system, but I believe the professional argument is much more important.

Our task will be to convince the legislators of the importance of *their* role in maintaining current good medical standards, rather than to risk diminishing the quality of health care in our state.

Norman A. Zlotsky, M.D.
President

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Reflections on Medicine

Emil von Behring and Diphtheria

ROBERT U. MASSEY, M.D.

A memory from medical school days that still can elicit a sense of dread is that of diphtheria. I recall standing, masked and gowned, at the foot of a narrow bed watching an emergency tracheotomy performed on a "mummied" nine-year-old. I knew that I could never do this, that here was the line that divided the real doctors from the pretenders, and that now was the time to quit while quitting was still possible. Too much for head, heart, and hands to learn, and I was probably not genetically or culturally equipped to practice medicine; after all, as far as I knew, none in my family had been a physician, maybe for good reasons.

Everything about diphtheria had seemed daunting; my own shots of toxin-antitoxin had left a peculiarly vivid memory. I am sure the TAT followed the bad news of a positive Schick. I have a picture-clear memory of our next door family doctor carefully injecting Schick toxin intradermally using an elegant, tiny gold needle which he had just boiled in a spoon over the flame of our gas stove. I recall the red spot on my arm that lasted for days and then peeled. A negative Schick, of course, was required for admission to kindergarten.

Mortality from diphtheria was high even after the general use of antitoxin. At the Herman Kiefer Hospital, the infectious disease hospital in Detroit, overall mortality from diphtheria between 1927 and 1936 was 12.1%, but a little over half the patients had had the mild, tonsillar type. One-fourth of the cases had nasopharyngeal diphtheria and that carried a 30.4% mortality. Hemorrhagic diphtheria, 1.2% of the total, carried a 97% mortality. This was all under nearly ideal conditions and with the proper use of antitoxin. Of course many patients were admitted after several days of croup or sore throat during which no one wanted to think about diphtheria. Prognosis depended on the day of the disease when the antitoxin was first given. And the antitoxin was not without serious risk; serum sensitivity had to be checked for and sometimes the patient desensitized. The epinephrine syringe was always at hand.

ROBERT U. MASSEY, M.D., Professor, Division of Humanistic Studies in Medicine, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

If you've read Sinclair Lewis's *Arrowsmith* you may remember Martin's terrifying night in the farmhouse with the little eight-year-old Mary Novak.

"He had to make a decision, irrevocable, perhaps perilous. He would use diphtheria antitoxin. But certainly he could not obtain it from Pete Yeska's in Wheatsylvania."

There followed the wild drive in the old Ford to get the antitoxin, the return, the intravenous injection, then "There was a gurgle, a struggle in which her face blackened, and she was still. ... Slowly the Novaks began to glower, ... Slowly they knew the child was gone." And then, as he was driving home through the night, "'I shall never practice medicine again,' he reflected."

It was just a hundred years ago this year that Emil von Behring left the Prussian army to begin his work as an assistant to Koch in the Institute of Infectious Diseases in Berlin. Klebs and Loeffler had identified the bacillus of diphtheria five years earlier, Roux and Yersin at the Pasteur Institute had demonstrated that a sterile filtrate from a diphtheria bacillus culture would produce the symptoms of the disease in animals, and in 1890 Fraenkel and Brieger demonstrated that this bacillus-free "toxalbumin" injected into guinea pigs would induce immunity to *C. diphtheriae*. Within days of the report, von Behring had shown that an animal injected with immune serum resisted infection, and an animal with the disease if treated with immune serum could be cured.

The first use of antitoxin in a child with diphtheria was on Christmas night, 1891, in von Bergmann's clinic in Berlin. In 1913 von Behring introduced his toxin-antitoxin mixture for active immunization, but immunization programs were not the rule in North America until the 1920s. Since then mortality rates have fallen from 20 per 100,000 to less than .006.

Emil von Behring shared the Nobel prize with Émile Roux in 1901; his name was among those of the 93 German intellectuals who signed the manifesto against the 1914 war. He died of pneumonia at Marburg, 31 March 1917. Antiserum for that disease, which would cut mortality in half, was still a decade or so away.

FREDERICK C. WEBER, JR., M.D.

1911 - 1988



Frederick C. Weber, Jr., M.D., of Athens, Vermont, formerly of Greenwich, died on 15 September 1988 while vacationing in Alaska. He had celebrated his 77th birthday on 12 July just prior to leaving for a fishing expedition. Cause of death was respiratory failure.

Dr. Weber had retired from the practice of internal medicine in 1986 and moved to Vermont with his wife, Janette Frissell Weber.

In 1971-72, Dr. Weber served as president of the Connecticut State Medical Society. In addition to being a member of the AMA, he had served on numerous committees of both the State Society and the Fairfield County Medical Association. He had been a delegate to the CSMS House of Delegates until his move to Vermont.

Dr. Weber served the profession in many capacities. In 1958-59 he was president of the Greenwich Medical Society; in 1965-66 he assumed the responsibility as president of the Fairfield County Medical Association. He was a CSMS associate councilor, 1963-64; CSMS secretary, 1968-69; vice president, 1969-70; and president elect, 1970-71.

From 1954 to 1960, Dr. Weber was a member of the Board of Health for the town of Greenwich.

Born the son of a physician in Washington, D.C., Dr. Weber received his undergraduate degree from Yale University in 1932. He completed his medical degree in 1936 at Johns Hopkins University School of Medicine; he was a member of both Phi Beta Kappa and Alpha Omega Alpha. He served his internship at Johns Hopkins from 1936 to 1937 and was an assistant resident in medicine at New York Hospital from 1937 to 1940, after which he opened his practice in Greenwich. From 1940 to 1942 and again from 1946 to 1950 he was an instructor in medicine at Cornell Medical School. He was board certified in internal medicine in 1943.

During World War II, Dr. Weber was a Lieutenant Colonel in the U.S. Army Medical Corps, serving in the southwest Pacific region.

Upon his return to Connecticut in 1946, Dr. Weber took an active leadership role at Greenwich Hospital, and served as director of the department of medicine from 1954 to 1960. In 1952 he was designated a fellow of the American College of Physicians.

He was appointed by the governor to the Connecticut State Medical Examining Board. He also devoted many hours to peer review at both the county and state level.

In his quiet manner, Dr. Weber was always concerned for his patients, his family and the standards of his chosen profession. Throughout his fifty years as a physician, he served as a mentor to many young physicians who trained under him.

Since retiring to an early-American farmhouse in an idyllic Vermont setting, Dr. Weber had excavated an old pond, had the dam rebuilt and stocked the pond with brook and rainbow trout. More recently he was in the process of rehabilitating an apple orchard.

Dr. Weber enjoyed the outdoors as a hunter and fisherman. He and Mrs. Weber had planned to do some salmon fishing in Alaska at the time of his death.

His survivors include his wife, two daughters, Susan Weber Plass of Sparta, New Jersey, and Sally N. Weber of Los Angeles, California; a son, Stephen L. Weber of Athens, Vermont; and a brother, Richard R. Weber of Scarsdale, New York.

P.H.M. and L.R.T.

The McConnell Case and the "Death with Dignity Statute"

Joseph M. Healey, J.D.

The McConnell case focuses attention on Connecticut's "Death with Dignity Statute"¹ and its implications for decisions at the end of life. This is the first case involving the statute to be reviewed by the Connecticut Supreme Court and two important questions are raised: (1) whether the statute requires that nonterminal patients be forced to accept artificial nutrition and hydration in all cases; (2) whether the statute so construed violates the constitutional rights of patients. The Connecticut Supreme Court has the opportunity to clarify these questions and to address the legal boundaries of this important area of public policy. Many Connecticut physicians hope that the Court will act decisively to provide such a clarification of their rights and responsibilities.

The first question involves issues of statutory construction. Determining the meaning of any statute can be a complicated process involving an after-the-fact acknowledgement of the intent of its proponents, recognition of the effect of amendments, and reconciliation of the perceptions of those who supported and opposed the legislation. Such complications are especially present in clarifying the meaning of the "Death with Dignity" statute.

This bill was the product of negotiations and compromises which make it difficult to conclude that there is a single, clear meaning which reconciles its conflicting provisions and purposes. What is in most states a patient rights statute, which describes the circumstances under which a currently competent patient may direct how care is provided should future incompetence prevent active participation in his or her self-determination, has become in Connecticut a physician and hospital immunity statute which describes how to avoid civil and criminal liability if a patient's wishes are followed. This reluctant acceptance of a patient's right to execute a living will is further diminished by a provision allowing the next of kin to veto the expressed wishes of the patient.

There is an inherent conflict between the overall goal of the legislation—the facilitation of patient self-determination—and the amendments to the proposal which

undermine the patient's right to self-determination. This conflict is further evident in the provisions of the statute that purport to treat artificial nutrition and hydration in a different manner from other forms of medical treatment. The statute seeks to protect the patient from undertreatment, yet pursues this laudable goal in a confusing and inappropriate manner by failing to distinguish between ordinary nutrition and hydration and artificial nutrition and hydration, by excluding nutrition and hydration from the definition of "life support system," and by apparently attempting to require the attending physician who does not deem the patient to be in a terminal condition to provide nutrition and hydration in every circumstance. Such failures to acknowledge that there are situations in which artificial nutrition and hydration are medical care which may be refused by the patient are inconsistent with an overall legislative goal of permitting, not restricting the exercise of patient self-determination.

The second question involves the extent to which the state could limit the exercise of a right to refuse treatment. Even if one finds that the statute on its face purports to require patients not in a terminal condition to accept nutrition and hydration, such a constraint does not appear to be grounded in any of the compelling state interests acknowledged by other courts as legitimate bases of state regulation. These interests include the state's interest in the preservation of life, the protection of third parties, the prevention of suicide, and the ethical integrity of the medical profession. Though there may be circumstances in which the first and second of these may justify some constraint on the individual's right of self-determination, it is difficult to conclude that an adult person of sound mind does not have the right to determine that he or she does not want to receive medical care or treatment of any sort should he or she be in a condition such as a persistent vegetable state, with no reasonable likelihood of regaining cognitive function. Such judgment seems clearly within the constitutionally protected area of individual self-determination.

Hopefully, the Supreme Court will affirm the patient's right of self-determination and end whatever confusion the "Death with Dignity" statute has caused.

REFERENCE

1. Connecticut General Statutes Sec 19A-570 *et seq.*

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

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July '89. Age 35. Presently in practice. AB cert. MD, Boston University, Boston, MA; Int. and Res. Carney Hospital, Boston, MA. Prefers group type practice in a medium to large-sized community. Write, Eric C. Hatton, M.D., 800 Rosewood Dr., Clovis, NM 88101.

Cardiology. Sept. '88. Age 34. Licensed in Connecticut. Nat'l bds. AB elig. MD, Instituto Tecnologico de Santo Domingo, Dominican Republic; Res., Salvador B. Gautier Hospital, Santo Domingo; Fellowship, Metropolitan Hospital Center, NY Medical College, NY, NY. Prefers any type practice in a small to medium-sized community. Write, Sergio R. Collado, M.D., 301 Post Rd., East, Apt. 19, Westport, CT 068800.

Cardiology. Dec. '89. Age 32. Flex. AB cert. MD, Government Medical College, Surat, India; Int., Detroit Macomb Hospital Corp., Detroit, MI; Res. and Fellowship, St. Joseph Mercy Hospital, Pontiac, MI; Prefers solo or associate type practice in a small to medium-sized community. Write, Mukeshchandra M. Patel, M.D., 900 East Blvd. South, Apt. F-124, Pontiac, MI 48053.

Gastroenterology. July '89. Age 28. Nat'l bds. AB elig. MD, Mount Sinai School of Medicine, NY, NY; Int. and Res., Long Island Jewish Medical Center, New Hyde Park, NY; Fellowship, Booth Memorial Medical Center, Flushing, NY. Prefers solo, group or associate type practice. Write, Jeffrey T. Dreznick, M.D., 63-53 Haring St., Apt 608, Rego Park, NY 11374.

Gastroenterology and Nutrition. July '89. Age 35. Nat'l bds. AB elig. D.O. College of Osteopathic Medicine and Surgery, Des Moines, IA; Int., Oakland General Osteopathic Hospital, Madison Heights, MI; Res., Henry Ford Hospital, Detroit, MI; Fellowship, Wayne State University, Detroit and Providence Hospital, Southfield, MI (Gast); University of California, David Medical Center, Sacramento (Nutr.). Prefers group, associate type practice in a large-sized community. Write, Curtis Freedland, D.O., 25601 Briar Dr., Oak Park, MI 48237.

Hematology/Oncology. Oct. '89. Age 31. Nat'l bds. AB cert. (IM); AB elig. (Hm/On). MD, Vanderbilt University, Nashville, TN; Int., Res., and Fellowship, Oklahoma University, Oklahoma City, OK. Prefers group, associate, institutional or solo type practice. Write, Richard J. Conklin, M.D., 244 Barrett Place, Edmond, OK 73034.

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BRIEF SUMMARY

CONTRAINDICATIONS

There are no known contraindications to the use of sucralfate.

PRECAUTIONS

Duodenal ulcer is a chronic, recurrent disease. While short-term treatment with sucralfate can result in complete healing of the ulcer, a successful course of treatment with sucralfate should not be expected to alter the post-healing frequency or severity of duodenal ulceration.

Drug Interactions: Animal studies have shown that simultaneous administration of CARAFATE (sucralfate) with tetracycline, phenytoin, digoxin, or cimetidine will result in a statistically significant reduction in the bioavailability of these agents. The bioavailability of these agents may be restored simply by separating the administration of these agents from that of CARAFATE by two hours. This interaction appears to be nonsystemic in origin, presumably resulting from these agents being bound by CARAFATE in the gastrointestinal tract. The clinical significance of these animal studies is yet to be defined. However, because of the potential of CARAFATE to alter the absorption of some drugs from the gastrointestinal tract, the separate administration of CARAFATE from that of other agents should be considered when alterations in bioavailability are felt to be critical for concomitantly administered drugs.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Chronic oral toxicity studies of 24 months' duration were conducted in mice and rats at doses up to 1 gm/kg (12 times the human dose). There was no evidence of drug-related tumorigenicity. A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment. Mutagenicity studies were not conducted.

Pregnancy: Teratogenic effects. Pregnancy Category B. Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to sucralfate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sucralfate is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Adverse reactions to sucralfate in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 2,500 patients treated with sucralfate, adverse effects were reported in 121 (4.7%).

Constipation was the most frequent complaint (2.2%). Other adverse effects, reported in no more than one of every 350 patients, were diarrhea, nausea, gastric discomfort, indigestion, dry mouth, rash, pruritus, back pain, dizziness, sleepiness, and vertigo.

OVERDOSAGE

There is no experience in humans with overdosage. Acute oral toxicity studies in animals, however, using doses up to 12 gm/kg body weight, could not find a lethal dose. Risks associated with overdosage should, therefore, be minimal.

DOSAGE AND ADMINISTRATION

The recommended adult oral dosage for duodenal ulcer is 1 gm four times a day on an empty stomach.

Antacids may be prescribed as needed for relief of pain but should not be taken within one-half hour before or after sucralfate.

While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been demonstrated by x-ray or endoscopic examination.

HOW SUPPLIED

CARAFATE (sucralfate) 1-gm tablets are supplied in bottles of 100 (NDC 0088-1712-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1712-49). Light pink scored oblong tablets are embossed with CARAFATE on one side and 1712 bracketed by C's on the other.

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Reference:

1. Eliakim R, Ophir M, Rachmilewitz D: *J Clin Gastroenterol* 1987;9(4):395-399.



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Effect of Aerobic Training on Left Ventricular Diastolic Filling

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ABSTRACT—The effects of aerobic training on left ventricular diastolic filling were determined and related to the effects on maximal oxygen uptake, left ventricular systolic function, and left ventricular mass. Nine untrained healthy males with a mean age of 32 years underwent a ten-week program of bicycle training. Echocardiographic left ventricular mass, maximal oxygen uptake, radionuclide-derived left ventricular ejection fraction, and average left ventricular filling rate were obtained before and after training. Training resulted in significant increases in maximal oxygen uptake (from 30 ± 6 (mean $\pm$ S.D.) to 40 ± 7 ml/kg/min, $p < 0.001$) and average left ventricular filling rate (from 2.04 ± 0.36 to 2.22 ± 0.31 end-diastolic volumes/sec, $p < 0.05$), but no changes in heart rate, systolic blood pressure, left ventricular ejection fraction, or left ventricular mass. These data indicate that short-term high-intensity aerobic training enhances average left ventricular diastolic filling independent of any change in left ventricular geometry, systolic function, heart rate, or blood pressure.

Introduction

THE functional and morphological cardiac responses to endurance training include an increase in maximal oxygen uptake ($\text{VO}_{2\text{max}}$), a lowering of the resting heart rate, and increases in left ventricular cavity dimensions and/or wall thickness.¹ Training-induced resting bradycardia with its attendant prolonged diastolic filling partly explains the resulting cardiac dilation. Since resting cardiac output is unaltered by training, stroke volume must increase to compensate for the lower heart rate.

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Training-induced cardiac enlargement serves as the predominant factor underlying the increase in stroke volume since ejection phase indices are relatively unaffected, but additional cardiac adaptations may also be important.¹

Recently, interest has focused on left ventricular diastolic function in athletes. Diastolic filling and ventricular stiffness have been found to be normal or facilitated in endurance-trained subjects with physiological hypertrophy²⁻⁶ which is in marked contrast to patients with pathological hypertrophy.⁷⁻¹¹ Enhanced left ventricular diastolic filling has also been demonstrated in athletes during exercise¹² and this may serve as an additional cardiac adaptation contributing to the increased stroke volume seen after endurance training. However, very little is known about the direct effects of training on diastolic function.¹³ The purpose of this study is to evaluate the effects of short-term aerobic training on left ventricular diastolic filling.

Materials and Methods

Subject Selection:

Nine healthy male volunteers aged 29-35 years without clinical evidence of heart disease were recruited from the hospital staff. None of the subjects had participated in endurance training for the past six months and none had been exercising for more than two hours per week. All subjects gave informed written consent and the experimental protocol was approved by the Human Research Review Committee of Mount Sinai Hospital. The physical characteristics of the subjects are summarized in Table 1. All subjects were tested for the following variables before and after their training program:

Estimation of Body Fat:

Six skinfold sites (chest, triceps, subscapular, abdomen, suprailiac, thigh) were measured in triplicate with a Lange caliper and the averages of each of the six measurements were summed for each subject. The height and weight of each subject were recorded. The skinfold data collected from these sites were used to estimate body fat according to a modification¹⁴ of the Jackson and Pollock equation.¹⁵ Lean body mass was determined by subtracting fat weight from the total body weight.

Echocardiography:

M-mode echocardiograms were obtained at rest by a

single experienced technician using standard techniques. Using the Penn Convention,¹⁶ posterior wall thickness, interventricular septal thickness, and left ventricular internal dimension at end-diastole were determined and averaged over several cardiac cycles. To minimize the variability in echocardiographic measurements, echocardiograms were coded and read blindly by one of us (AR) without knowledge of subject identity or training status. Left ventricular mass was calculated by the method of Devereaux and Reichek¹⁶ and derived measurements were indexed to body surface area.

Maximal Oxygen Uptake:

All subjects underwent cardiopulmonary exercise testing prior to and after completion of their conditioning program. The exercise test protocol was to pedal an electronic Mijnhardt KEM-2 Cycle-Ergometer against a continuous 30 watt/minute ramp until exhaustion. Maximal oxygen uptake was determined using a model MGA 1100 Perkin-Elmer mass spectrometer for analysis of oxygen fractions of expired air and a Hans Rudolph pneumotachograph for gas volume measurement interfaced with a Medical Graphics Corporation model 2000 wave-form analyzer and Tektronix 4052A computer for data gathering and analysis. Oxygen consumption was determined on a breath-by-breath basis continuously during the exercise protocol. Subjects were exercised to exhaustion, and the highest value was taken as peak oxygen uptake.

Radionuclide Studies:

Left ventricular diastolic function was determined by gated equilibrium radionuclide ventriculography at rest. Each subject's red blood cells were labeled with 20-30mCi of Tc-99m pertechnetate after a standard injection of stannous pyrophosphate. All radionuclide studies were obtained in the modified left anterior oblique projection by a single experienced technologist using an updated Searle PhoGamma/HP gamma camera interfaced with a Technicare MCS 560 computer. Generation of time-activity curves and calculation of left ventricular ejection fractions were made by an operator-dependent variable left ventricular region of interest after spatial and temporal smoothing of the data using a conventional software program (MICA - Technicare Corp.). The analysis was performed without knowledge of subject identity or training status. Average left ventricular filling rates, in counts per second, were derived by the least squares fit techniques using the rapid diastolic portion of the time-activity curve (CURFIT - Technicare Corp.) as validated and applied by Smith et al¹⁰ and in a manner similar to that of Lee et al.¹⁷ Values were then normalized for the number of left ventricular counts at end-diastole and expressed as end-diastolic volumes per second (EDV/sec).

Training Program:

The subjects trained intensely for ten weeks on an upright bicycle ergometer 45 minutes per day, four days per week. Each session consisted of a five-minute warm-up period followed by 30 minutes of pedaling at workloads adjusted to maintain a minimum of 80% of the subject's maximal heart rate determined on the pre-

training cardiopulmonary stress test. Each conditioning session was followed by ten minutes of cool-down. The exercise sessions were monitored on a weekly basis by one of the study investigators to assure compliance with the exercise protocol, and a log of maintenance target heart rates was recorded by each of the subjects.

Other Measurements:

Heart rates were calculated from the average RR interval taken from a several-minute interval during the radionuclide study. Three resting upright blood pressures were recorded and averaged. Body surface area was determined by standard means.

Statistical Analysis:

Means and standard deviations of pre- and posttraining measurements were computed; differences between mean values were analyzed by use of a paired t-test for correlated samples. Statistical significance was defined as $P<0.05$.

Results

Adaptations to Training:

Changes in Maximal Oxygen Uptake: The training program resulted in a significant increase in maximal oxygen uptake from 30 ± 6 (mean $\pm$ standard deviation) to 40 ± 7 ml/Kg/min, ($p<0.001$) (Table I). The resting heart rates and systolic blood pressures were unaltered by the training program, and body surface area decreased (Table I).

Table I
SUBJECT CHARACTERISTICS
(n=9)
32 $\pm$ 3 years

AGE	Pre	Post
Heart rate (beats/min)	69 $\pm$ 11	66 $\pm$ 8*
Systolic blood pressure (mmHG)	126.0 $\pm$ 12.4	120.9 $\pm$ 7.6*
Body Surface Area (m ²)	2.07 $\pm$ 0.20	2.02 $\pm$ 0.18 ⁺
Lean body mass (lbs)	137 $\pm$ 21	134 $\pm$ 18*
Maximal O ₂ uptake (ml/kg/ min.)	30 $\pm$ 6	40 $\pm$ 7 [‡]

All values are expressed as the mean $\pm$ 1 standard deviation.
*Not significant; + $p<0.01$; ‡ $p<0.001$.

Changes in Echocardiographic Measurements and Derived Left Ventricular Mass: There was no significant change in end-diastolic left ventricular internal dimensions, posterior wall thickness, or derived left ventricular mass after ten weeks of the training program (Table II).

Changes in Radionuclide Measurements: Average left ventricular filling rate increased significantly from a pre-training mean of 2.04 ± 0.36 to a posttraining value of 2.22 ± 0.31 EDV/sec., $p<0.05$ (Table II, Fig. 1). In these subjects, eight of nine (89%) increased their average left ventricular filling rate after training. Examples of time-activity curves pre- and posttraining for a representative subject are shown in Figure 2. Systolic function as measured by the left ventricular ejection fraction did not change after training.

Discussion

This study evaluated the effects of short-term high

Table II
ECHOCARDIOGRAPHIC AND
RADIONUCLIDE MEASUREMENTS

	Pre	Post
LVEDDI (cm/m ²)	2.33±0.25	2.37±0.20*
PWThI (cm/m ²)	0.46±0.08	0.43±0.09*
LVMI (g/m ²)	88±15	87±17*
LVEF (%)	64±9	66±7*
LVFR _{av} (EDV/sec)	2.04±0.36	2.22±0.31+

All values are expressed as the mean ± 1 standard deviation. *Not significant; +p<0.05. LVEDDI=left ventricular end-diastolic dimension index; PWThI=posterior wall thickness index; LVMI=left ventricular mass index; LVEF=left ventricular ejection fraction; LVFR_{av}=average left ventricular filling rate.

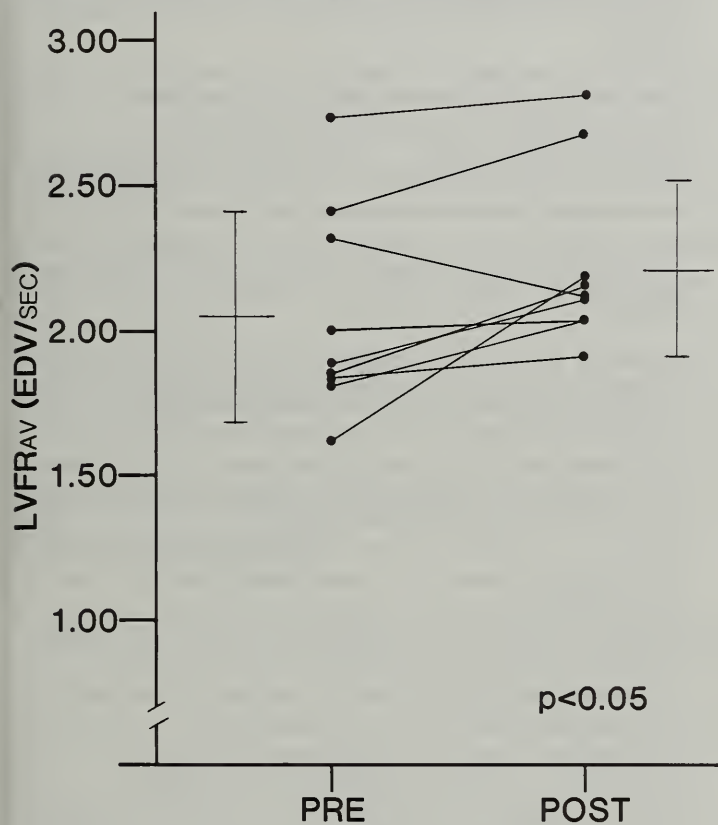


Figure 1

Individual values, mean values, and standard deviations of the average left ventricular filling rates (LVFR_{av}) expressed as end-diastolic volumes per second (EDV/sec) pre- and posttraining for the subjects.

intensity aerobic training on average left ventricular diastolic filling, heart rate, maximal oxygen uptake, left ventricular systolic function, and left ventricular dimensions and mass. Short-term high intensity aerobic training augmented average left ventricular diastolic filling and increased maximal oxygen uptake. The increase in average left ventricular diastolic filling seen after short-term aerobic training occurred without any change in resting heart rate, blood pressure, left ventricular systolic function, or left ventricular dimension and mass. The present findings suggest that enhancement of left ventricular diastolic filling may be an important functional cardiac adaptation to aerobic training.

Recently, interest has focused on diastolic function in athletes with physiologic hypertrophy. Using digitized echocardiography, Shapiro and Smith studied the effects

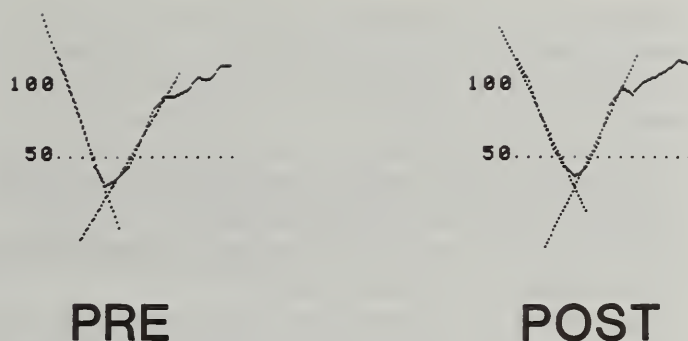


Figure 2

Actual radionuclide time-activity curves with computer derived slope of the rapid filling phase for a representative subject pre- and post-aerobic training. Training resulted in an increased average left ventricular filling rate (1.63 to 2.19 end-diastolic volumes/sec) and a slight reduction in ejection fraction (65% to 60%). After training, the heart rate increased from 58 to 63.

of six weeks of high intensity running on left ventricular structure and diastolic function and noted a 30% increase in posterior wall thickness without any detectable changes in relaxation or diastolic function.¹³ Despite the increase in maximal oxygen uptake induced by our bicycle training program, there was no increase in left ventricular dimensions or mass after ten weeks of training, but average left ventricular diastolic filling improved significantly. Differences in the subjects studied, type, intensity, and frequency of the training programs and methodology used to determine left ventricular diastolic filling properties may explain the variability in the results. We² and others³⁻⁶ have also shown that high endurance athletes with physiological hypertrophy have normal diastolic function and ventricular stiffness which is in contrast to the findings in patients with pathological left ventricular hypertrophy associated with left ventricular pressure overload.⁷⁻¹¹ In our previous study, there was a slight but insignificant trend for average filling rates to be higher in the athletes with a greater left ventricular mass index.² Doppler assessment of the ratio of early-to-late peak diastolic velocities suggests enhanced function in ultraendurance trained triathletes.⁵ In another group of aerobically-trained athletes, Matsuda et al found that echocardiographically determined left ventricular early diastolic filling was enhanced both at rest and during exercise compared to sedentary healthy subjects.¹² These findings demonstrate that left ventricular hypertrophy by itself is not associated with impaired diastolic function and as suggested by the present study and those previously cited, chronic and short-term aerobic training may improve diastolic performance. Enhanced diastolic filling may facilitate the trained heart to increase stroke volume at rapid heart rates when the diastolic filling period is shortened, as occurs during exercise.

In this study, we used average left ventricular filling rate as an index of left ventricular diastolic function. Average left ventricular filling rates have been used reliably to compare diastolic function in patients with pathologic¹⁰ and physiologic² hypertrophy with normal subjects, to assess the effects of antihypertensive therapy on the heart,¹⁸ and for the early detection of doxorubicin

cardiotoxicity.¹⁷ These results are qualitatively similar to those obtained using peak diastolic filling rates derived by radionuclide techniques⁹ and echocardiography.³ In addition, average rapid left ventricular filling rates measured with a nonimaging nuclear probe correlate well with those calculated with a gamma camera.¹⁰ Use of average left ventricular filling rates makes no assumption on how the left ventricle fills since all phases of rapid diastolic filling are weighted equally.

Even though our short-term high-intensity aerobic exercise program failed to induce physiologic hypertrophy, a significant increase in maximal oxygen uptake was elicited, confirming that physiological adaptations can precede cardiac morphological changes. Accompanying the increased maximal oxygen uptake was a significant augmentation of the average left ventricular diastolic filling rate. Since those factors known to influence the rate of left ventricular rapid diastolic filling such as age, heart rate, blood pressure, left ventricular volume, mass, contractility, and loading conditions¹⁹⁻²² were unaltered by the training program, enhancement of diastolic filling by aerobic training can be viewed as an independent functional myocardial adaptation. Our preliminary results need to be confirmed in a larger randomized, controlled study using additional methods of evaluating diastolic function.

Data derived from experimental studies have shed some light on the possible mechanisms by which physical training facilitates left ventricular diastolic filling. Isolated hearts from swim-conditioned rats demonstrate a more rapid rate of decline of left ventricular pressure during diastole compared with hearts from sedentary animals.²³ Penpargkul et al have demonstrated enhanced calcium uptake and binding in the sarcoplasmic reticular vesicles isolated from trained rats.²⁴ It is speculative that enhanced diastolic filling resulting from training may be related to an increase in the rate of calcium uptake by the sarcoplasmic reticulum of conditioned hearts. Colan et al have suggested that relaxation may be facilitated.³

In conclusion, short-term high-intensity aerobic training augments average left ventricular diastolic filling prior to inducing structural cardiac adaptations. Enhanced left ventricular diastolic filling may be an important cardiac adaptation underlying the improved cardiovascular fitness of aerobically-trained athletes. The results of this study are provocative in terms of a potential therapeutic role of physical training in patients with diseases characterized by abnormal diastolic filling such as coronary artery disease and hypertension.

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Mobile Mammography: The First Six-Months Experience at Mount Sinai Hospital

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ABSTRACT—Mount Sinai Hospital's Mobile Mammography Program, BreastCheck, is designed to screen large numbers of women for breast cancer in the greater Hartford area. Despite the American Cancer Society recommendations for screening mammography, many physicians still are not complying with these guidelines. This report details our first six-months experience. Two thousand two hundred thirty women were screened, 38 women had biopsies, and 14 cancers were detected. The overall rate of breast cancer detection is 6.3/1,000 which compares favorably with the rates from the National Breast Cancer Demonstration Detection Project (BCDDP) of 4.6/1,000.

Underutilization of Mammography

BREAST cancer is the second most common cancer among women. Despite the fact that screening for breast cancer has been shown to decrease mortality rates, only 5% to 15% of women in the United States have had a mammogram.¹ The American Cancer Society (ACS) advocates screening for asymptomatic women beginning with baseline mammograms at age 35-40, every one to two years from age 40-49, and yearly beginning at age 50. "Lack of physician compliance with these guidelines is one of the major reasons for underutilization. The high cost of the procedure, of \$110-\$220, is the second most important factor. Other reasons include lack of patient knowledge, and fear of the procedure itself."²

BreastCheck: Procedure

Mount Sinai Hospital's mobile mammography service, **BreastCheck**, addresses several factors affecting utilization. Women may be either physician-referred or self-referred. If self-referred, the patient must give the name of a doctor to whom she wishes the report sent. This physician is frequently her primary care physician or gynecologist. If the patient has no doctor, she is given

a list of surgeons to choose from, depending on her locale, and compiled with the help of the chiefs of surgery at area hospitals and with the consent of each of the participating physicians.

The 34-foot mobile coach was designed to make breast cancer screening available in a convenient setting and at a low cost. The cost is \$55, payable by credit card, check, or money order, and, as of 1 October 1988, will be covered by most health insurance plans. The coach visits shopping areas, health care facilities, school systems, corporations, smaller businesses, women's groups, and health fairs. BreastCheck provides free screening examinations to indigent women one day each month. Appointments are made in advance, although walk-in patients are accommodated on a space available basis. Patients are scheduled fifteen minutes apart. A seven-minute videotape on breast self-examination, (BSE), is available for viewing.

Specially trained female radiologic technologists perform the mammogram on a low-dose, state-of-the-art, mammography machine. The standard two views of each breast, the craniocaudad, and the 45 degree medio-lateral oblique view are obtained on the coach. The films are batch-processed at the end of the day, and read the following morning by radiologists with special training and interest in mammography.

Since this is a screening facility, all demographic data are entered on a dedicated computer which permits follow-up and statistical analysis. Almost all reports are computer-generated. The patient must also sign a consent form that explains that mammography is only one part of the diagnosis of breast disease; that monthly breast self-examination and yearly physical examination by her physician, as well as following the ACS guidelines, constitute important parts of total breast care.

If the patient's mammogram is normal, she receives a form letter along with the recommendation to follow the ACS guidelines, to perform BSE, and to see her physi-

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cian yearly; the patient's physician receives a computer generated report. If the mammogram is abnormal, the doctor's report includes recommendations for biopsy, magnification views, ultrasound, or follow-up in six or 12 month intervals. Likewise, if abnormal, the patient receives a letter stating that she should have further studies. If a cancer is suspected, the patient receives a letter stating that a significant abnormality has been detected on her mammogram and that she should arrange to see her physician. In addition, her physician is immediately contacted by telephone. In the cases where a cancer is suspected, or when an ultrasound or magnification view is recommended, letters are sent by certified mail to both the patient and her physician.

BreastCheck is designed as a screening facility. Our intent is to see large numbers of women, provide mammograms economically, and determine whether or not an abnormality is present. We do not attempt to characterize an abnormality.

Results

In the first six months, 11 patients had suspicious mammograms. Three of these patients are being followed by a surgeon; the other eight have been diagnosed by biopsy to have carcinoma. Another 118 patients have received the ultrasound or magnification letters which resulted in another 30 biopsies. Six more cancers were detected after these additional studies, and the other 24 biopsies were benign. Sixty-two patients were sent letters advising six-month follow-ups, and 101 patients were advised to return in a year.

Thus, a total of 14 cancers were detected among 2,230 women for a rate of 6.3/1,000. This figure is higher than the figure of 4.6/1,000 that resulted from the National Breast Cancer Detection Project, which included the screening of 280,000 women.³ The cancer rate was 14 in 38 biopsies, or 36%.

Table 1 compares our experience to the experience at Mallinckrodt Institute of Radiology (MIR), Washington University in St. Louis:

Table 1

	Total	Recalls	Cancers	Rate/1,000	Biopsy	% Cancers ^a
BRSTCK	2,230	118	14	6.3	38	36%
MIR	2,275	122	13	4.7	73	17.8%

The total number of recalls and cancers are similar, but at MIR almost twice the number of biopsies were performed, and almost half the percentage of malignancies found as compared to BreastCheck.

Compliance To Screening Among Connecticut Women

Of the 2,230 women screened, 859 or 37% had had a previous mammogram as opposed to the national figure of 5% to 15% (Table 2). As expected, the lowest age

group, 35-39, had the lowest percentage of previous mammographies, with the incidence of previous mammography rising with age. Table 3 shows that seven out of 14 women, or 50% of those women with positive biopsies, had previous mammograms. However, among

Table 2
Previous Mammograms

Age Group	Yes		No		Total by Age	
	No.	%	No.	%	No.	%
35-39	46	14%	282	86%	328	15%
40-49	190	32%	400	68%	590	26%
50-59	280	51%	270	49%	550	25%
60-69	230	45%	281	55%	511	23%
70+	113	45%	138	55%	251	11%
All Ages	859	37%	1,371	63%	2,230	100%

those women with previous mammography, the earlier examination had been performed on the average of 7.4 years ago, with the average age being 64.7 years. Thus, while more women in Connecticut are having mammograms compared to the national average, women are clearly not adhering to the intervals for screening set by the American Cancer Society.

Table 3
Positive Biopsies

Previous Mammograms			No Previous Mammograms	
Patient	Age	When	Patient	Age
IB	57	6 yrs	CL	38
SZ	66	3 yrs	MD	52
MS	67	1.5 yrs	JG	57
MB	67	10 yrs	AD	66
FH	71	8 yrs	AH	67
AC	74	3 yrs	MM	70
MC	77	20 yrs	RS	77

Conclusions

The Mount Sinai Hospital Mobile Mammography program, **BreastCheck**, has been valuable not only for screening large numbers of women for breast cancer, but has also increased the awareness of breast disease among women. Our rate of cancer detection, 6.3/1,000, and our percentage of malignancies per total number biopsies, 36%, demonstrate the effectiveness of our BreastCheck program.

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Abstracts by Residents and Fellows

AMERICAN COLLEGE OF PHYSICIANS, CONNECTICUT CHAPTER

FOREWORD: The American College of Physicians, Connecticut Chapter, held its annual meeting on 21 October 1988 at Danbury Hospital. As part of this program, five prize winning abstracts by Associates of the College were selected for presentation. These abstracts, whose first authors are medical residents, are printed below. We applaud the support given to the authors by members of their teaching faculties. With this, the third collection, we continue an annual tradition among the teaching hospitals of our state.

Jonathan Alexander, M.D., FACP, Scientific Program Committee and Joseph L. Belsky, M.D., FACP, ACP Governor for Connecticut, Department of Medicine, Danbury Hospital.

Cerebellar Venous Infarcts

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Cerebellar infarcts are thought of as occurring in the elderly, and are usually secondary to vertebral or basilar artery thrombosis. Since these vessels also supply the brainstem, these types of infarcts are associated with a high degree of morbidity and mortality. With the increasing use of birth control pills, a new type of cerebellar infarct is being seen, a cerebellar venous infarct. Although it presents in the same manner as a cerebellar arterial infarct, if recognized early, the venous infarct can be treated and its course can be altered.

A 28-year-old white female who was taking oral contraceptive pills and had no other risk factors for venous

thrombosis was diagnosed as having a right cerebellar infarct secondary to sigmoid vein thrombosis. Dizziness and signs of cerebellar dysfunction progressed to left hemiparesis, coma, and respiratory failure. She recovered in six days with supportive therapy and full anticoagulation.

It is important to consider venous thrombosis in the differential diagnosis of a young woman taking birth control pills and presenting with signs and symptoms of a cerebellar stroke; early institution of heparin may result in complete resolution of this otherwise progressive and potentially fatal disease.

Type III Membranoproliferative Glomerulonephritis in Primary Sjogren's Syndrome

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Glomerulonephritis (GN) is a rare complication of primary Sjogren's syndrome (PSS). When GN does occur, it is usually due to membranous, focal proliferative or membranoproliferative lesions. We report for the first time the occurrence of Type III membranoproliferative glomerulonephritis (MPGN) in association with PSS. The patient was a 72-year-old white female with a ten-year history of PSS who presented with acute renal insufficiency. The patient did not fulfill the diagnostic criteria for SLE. Although an ANA was positive at a dilution of 1:1,280 in a homogenous pattern, LE prep,

anti-ds DNA, Sm, and RNP antibodies were negative. Anti-SSA (Ro) and anti-SSB (La) antibodies were present. Renal biopsy revealed Type III MPGN, characterized by prominent mesangial cell interposition and both subepithelial and subendothelial electron-dense deposits.

There have been fewer than 20 reported cases of GN in PSS, only three of which have been MPGN. We report a case of PSS complicated by Type III MPGN, a specific type of mesangiocapillary GN never before recognized in this setting, and describe a clinical course characterized by rapidly progressive renal failure.

Adult Reye's Syndrome: Report of a Case*

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There have been over 3,500 cases of Reye's syndrome reported to the CDC since 1973. The use of aspirin at the time of a prodromal viral illness has been statistically associated with the syndrome. Reye's syndrome presents as an acute progressive encephalopathy with varying levels of coma and a normal CSF. Hepatic transaminases are elevated, and the AST is usually elevated three to 30 times normal. Histological changes seen on liver biopsy are characterized by microvesicular intrahepato-

cyte lipid deposition, which is rarely found in other diseases.

The syndrome has rarely been reported to occur in adults older than 18 years. We report the 21st case of Reye's syndrome occurring in an adult, which initially presented as acetaminophen toxicity but was shown to be Reye's syndrome on histological examination of the liver.

*Case report published in *Connecticut Medicine*, January 1989.

Temporal Arteritis and Autoimmune Thyroid Disease

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A 72-year-old white female was seen with headache, proximal muscle weakness, and erythrocyte sedimentation rate of 130 mm/hr. She had undergone subtotal thyroidectomy for Hashimoto's thyroiditis 18 years previously. She had evidence of frank hypothyroidism, impaired vision in right eye, and proximal muscle weakness mainly involving the shoulders. A right temporal artery biopsy was consistent with giant cell arteritis. Antithyroglobulin antibodies were present at a titer of 1:320. Other laboratory findings were as follows: hemoglobin, 9.9 mg/dl; alkaline phosphatase, 302 I.U.; GGTP, 120 I.U.; C3, 131 mg/dl; C4, 83 mg/dl; TSH 50 μ IU/ml;

T4 3.3 μ Ig/ml. High dose intravenous steroids followed by thyroid replacement resulted in rapid recovery of vision and weakness as well as decrease in ESR to 30 mm/hr after four months.

Temporal arteritis is associated with circulating immune complexes. Its association with various autoimmune diseases have been emphasized in the literature. Graves' disease and primary hypothyroidism are previously reported in association with temporal arteritis. To my knowledge this is the first case of temporal arteritis reported in a patient with biopsy proven Hashimoto's thyroiditis and circulating antithyroid antibodies.

Testicular Feminization Presenting in a 78-Year-Old*

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Testicular Feminization Syndrome (TFS) is an inherited sex-linked recessive disorder characterized by male genotype and female phenotype secondary to end-organ insensitivity to androgens. The majority of cases present before age 30 with inguinal masses or primary amenorrhea or both.

A 78-year-old phenotypic female underwent an emergency reduction of an incarcerated right inguinal hernia. A mass excised at the tip of the hernia sac revealed atrophic testicular tissue with hyalinization of the tubules, interstitial fibrosis, Leydig cell hyperplasia, and an epididymis. The cytogenetics revealed 96% XY, confirming the previously unsuspected diagnosis of TFS. The patient

revealed that as a child she had been treated for hernia, and in adolescence she had failed to menstruate. She was told by her physicians that she had "female problems." Eleven years prior to this admission she had noticed a right inguinal hernia that periodically recurred.

Ten cases of TFS have been reported in the world literature presenting at age 50 or older, with only two older than 65. We believe that this patient is the oldest reported in the North American literature. Prior to this admission her last comprehensive medical evaluation had been in 1930, more than two decades before the recognition and understanding of TFS.

*Case report published in *Connecticut Medicine*, October 1988.

Important Advances in Clinical Medicine

Pathology

The Scientific Board of the California Medical Association presents the following inventory of items of progress in pathology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers, or scholars to stay abreast of these items of progress in pathology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Pathology of the California Medical Association and the summaries were prepared under its direction.

Platelet Antibodies

THROMBOCYTOPENIA may occur as the sole manifestation of disease or may be due to another disorder. The management of either primary or secondary thrombocytopenia depends on correctly identifying the casual pathophysiologic processes. Over the past decade a number of research laboratories have provided data to strongly support the hypothesis that primary isolated thrombocytopenia in adults—idiopathic thrombocytopenia purpura—is immune-mediated and in many cases may be more correctly termed autoimmune thrombocytopenia purpura. The development of sensitive assays that directly measure platelet-associated immunoglobulin (PAIg) corroborated earlier studies which suggested that this disorder is due to the deposition of immunoglobulin on the platelet surface, leading to the accelerated clearance of sensitized platelets. The ability to directly measure PAIg, in contrast to the earlier tests for detecting serum antiplatelet factors, has increased the sensitivity from 60% to greater than 90% with 93% specificity for detecting immune-mediated platelet destruction.

The increased diagnostic sensitivity has raised new questions concerning the specificity of elevated PAIg levels. It is now well recognized that increased PAIg can occur in thrombocytopenia associated with a wide variety of disorders, including systemic lupus erythematosus, lymphoma, carcinoma, Hodgkin's disease, the acquired immunodeficiency syndrome, and Hashimoto's thyroiditis. Elevated PAIg levels also may be associated with qualitative platelet dysfunction without concurrent

thrombocytopenia. Thus, elevated PAIg levels are not specifically associated with isolated autoimmune or idiopathic thrombocytopenia purpura. In most cases, it is unclear whether PAIg noted in either autoimmune thrombocytopenia purpura or the secondary disorders is specifically directed against a platelet antigen or is nonspecifically deposited on the platelet surface as part of an immune complex. In several recent reports the use of immunoblot techniques has identified PAIg directed against integral platelet proteins in some patients with autoimmune thrombocytopenia purpura. A recent study using monoclonal reagents for the detection of cell-associated immunoglobulin has provided stronger evidence that the presence of elevated levels of PAIg—more than 800 molecules of IgG per platelet—is physiologically consistent with currently understood immune-mediated clearance of other blood cells, and this concentration of cell-associated immunoglobulin is not observed in patients with nonimmune thrombocytopenia.

Each of the different techniques described to measure PAIg requires isolating platelets from whole blood, which may be difficult in patients with severe thrombocytopenia. Newly described fluorescence-activated flow cytometric assays and radioactive immunologic assays, however, exhibit adequate sensitivity even when few platelets are available. Indirect tests may be useful to diagnose neonatal isoimmune thrombocytopenia, post-transfusion purpura, or transfusion-induced alloimmunization. Indirect assays for determining suspected drug-dependent immune thrombocytopenia have had disappointing results due to the inability to solubilize drugs and do the assays under physiologic conditions. In sum-

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mary, the direct measurement of platelet-associated immunoglobulin is useful in establishing the diagnosis of immune-mediated platelet destruction and in choosing among various therapeutic alternatives during the course of these disorders.

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Fine-Needle Aspiration Biopsy of Lymph Nodes

FINE-NEEDLE ASPIRATION (FNA) or aspiration biopsy cytology of lymph nodes is done in patients presenting with persistent lymphadenopathy for which no obvious explanation exists, to stage patients with previously diagnosed malignancy (including malignant lymphoma), and to monitor for recurrence and progression of disease. Within this setting, a diagnosis of infection, reactive hyperplasia, malignant lymphoma, and metastatic tumor is sought.

The diagnosis of metastatic carcinoma usually is straightforward, as is the diagnosis of many reactive, inflammatory, and granulomatous disorders. The use of lymph node FNA for the primary diagnosis of malignant lymphoma has proved more challenging. For this reason, a confirmatory surgical biopsy is done at most hospitals in which a cytologic diagnosis of malignant lymphoma has been made or is suspected. This may not be necessary in selected cases at centers with broad experience in the diagnosis of lymphoproliferative disorders, especially when ancillary market studies are available to confirm the cytologic interpretation.

One argument for following lymph node FNA with a biopsy is to assess a nodular or diffuse pattern of infiltration, a distinction that carries therapeutic and survival implications based on the grading system enumerated in the National Cancer Institute (NCI) working formulation for non-Hodgkin's lymphomas.

Surgical biopsy must be done in cases of malignant lymphoma of predominantly small cleaved cell type (poorly differentiated lymphocytic lymphoma) and in cases of malignant lymphoma of mixed small cleaved and large cell type. Because these lymphomas show a spectrum of cell size, they may present a diagnostic problem on aspiration biopsy. Furthermore, they are classified as either low-grade or intermediate-grade lymphomas based on the biopsy assessment of a nodular or

diffuse pattern. Malignant lymphoma of small lymphocytic cell type (well-differentiated lymphocytic lymphoma), chronic lymphocytic leukemia, and malignant lymphoma of small lymphocytic-plasmacytoid type are low-grade malignant disorders but are difficult to diagnose unequivocally without the benefit of biopsy or ancillary marker studies. On the other hand, a biopsy would not be necessary to grade malignant lymphomas of large cell type, which are classified as intermediate grade whether nodular or diffuse. Large cell malignant lymphoma; malignant lymphoma, immunoblastic (immunoblastic sarcoma); malignant lymphoma, lymphoblastic (convoluted and nonconvoluted T-cell lymphoma); and malignant lymphoma of small noncleaved cells (Burkitt's) are all high-grade lymphomas according to the NCI working formulation and represent lymphomas that can be diagnosed by fine-needle aspiration.

Although centers with expertise in hematologic disorders may not require a confirmatory surgical biopsy in the FNA diagnosis of several types of malignant lymphoma, hospitals that have limited experience in this discipline should continue to use confirmatory surgical biopsy for diagnostic accuracy rather than relying on aspiration cytology alone.

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Biopsy Findings in Liver Transplant Patients

IN THE PAST FEW YEARS, orthotopic liver transplantation has become a relatively common therapy for a wide variety of both pediatric and adult liver diseases. Despite improved surgical and immunosuppressive techniques, patients undergoing this procedure are vulnerable to numerous complications involving transplantation-associated injury to the donor organ, infection, exacerbated by immunosuppression, biliary obstruction or leaks, vascular occlusion, and acute and chronic rejection. Liver biopsy has been shown to be an important adjunct to radiologic and serologic studies in these patients and is essential in discriminating between rejection and ischemic injury, two of the most common causes of graft dysfunction, as well as sometimes identifying viral infections in these immunosuppressed patients.

Acute rejection is histologically characterized by a mixed inflammatory infiltrate of the portal tracts composed primarily of T cells but with significant proportions of plasma cells, neutrophils, and eosinophils as well. These inflammatory cells are frequently found intimately associated with the epithelial cells lining the small interlobular bile ductules and the endothelial cells of the portal and centrilobular blood vessels (endotheliitis). This association is believed to be due to the stronger expression of major histocompatibility complex antigens by the bile duct and endothelial cells when compared with the hepatocytes. As a consequence, in most cases of rejection the bile ductules will show evidence of injury or regeneration while hepatocyte necrosis is not a prominent feature. Biliary epithelial injury can occasionally become so severe that most of the ductules will be completely destroyed over a long-term course ("vanishing duct syndrome"), a condition usually requiring retransplantation. Chronic injury to the liver vasculature has also been reported, with arteriolar thickening, fibrointimal hyperplasia of the large arteries, and the accumulation of subintimal foam cells in the hilar vessels with partial occlusion.

Ischemic injury to the liver is the second most common source of acute graft dysfunction and manifests four basic patterns on liver biopsy—focal infarcts, massive centrilobular necrosis, diffuse individual hepatocyte necrosis, and centrilobular hepatocyte ballooning. Focal infarcts occur as a result of ischemia of a specific portion of the liver either perioperatively or from postoperative vascular occlusion. They can vary in size and distribution, histologically showing confluent tissue necrosis with adjacent viable tissue; because of the focal nature of this lesion, a single liver biopsy may not detect it. The clinical sequelae of infarction depend on its extent and whether the necrotic tissues becomes secondarily infected.

Generalized, massive centrilobular necrosis is the result of diffuse liver injury, such as severe hypotension; this histologic finding usually leads to retransplantation. Diffuse, scattered, individual hepatocyte necrosis without inflammation is also a pattern of generalized ischemic injury, and depending on the severity of the insult there may be only a few necrotic cells within the lobule or numerous necrotic cells followed within three days by generalized graft destruction. Less severe generalized ischemic injury results in centrilobular hepatocyte "ballooning" in which liver cells around the central vein become notably swollen, with clear, "hydropic" cytoplasm. In most cases this swelling resolves without sequelae; in severe cases, however, there may be eventual centrilobular hepatocyte loss followed by pronounced cholestasis without apparent duct obstruction.

Viral infection clinically mimicking rejection or ischemia can be detected by biopsy in many cases. The most common virus is cytomegalovirus, but herpesvirus, adenovirus, and hepatitis B virus have also been described. Characteristic viral inclusions or patterns of

necrotic hepatocytes in association with inflammatory cells are clues to viral infection. Immunohistochemical stains and DNA hybridization studies can also be used on the biopsy tissue to detect viral infection.

Although the histologic patterns have been described individually, rejection, ischemia, and viral infections can occur simultaneously, with each contributing to a varying degree to the extent of liver injury.

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The Molecular Pathology of Prion Diseases

NEW PATHOGENETIC MECHANISMS are being discovered for the group of central nervous system (CNS) diseases that includes Creutzfeldt-Jakob disease, the Gerstmann-Straussler syndrome, and kuru in humans and scrapie in animals. These disorders have been grouped together because they have similar clinical, genetic, and histologic features—spongiform degeneration of neurons, astrocytic gliosis, and amyloid plaque formation—and because each is infectious. Originally it was postulated that they were caused by an atypical virus because of the small size of the infectious particle predicted from experimental studies and the absence of histopathologic features characteristic of viral infections. That possibility, however, is now considered unlikely because of studies at the University of California at San Francisco showing that highly purified preparations of the scrapie agent consist almost entirely of a single protein and no detectable nucleic acid. For this reason, the smallest infectious particle was termed a "prion" and the protein associated with infectivity was termed the "prion protein."

Although the structure of the prion and the precise role of the prion protein in infectivity are not known, it has been learned that the prion protein is an abnormal derivative of a normally expressed CNS nerve cell sialoglycolipoprotein. The normal isoform is synthesized continuously in hamster nerve cells, is highly susceptible to proteinase K digestion, and turns over rapidly. In contrast, the abnormal isoform resists proteinase K diges-

tion, turns over slowly, and accumulates in the brain during scrapie. Moreover, the abnormal isoform of the prion protein accumulates precisely in those regions of the gray matter where spongiform degeneration of nerve cell processes and reactive astrocytic gliosis are greatest. It also polymerizes into the filaments that form the amyloid plaques characteristic of these diseases.

Evidence indicates that a human isoform of the scrapie prion protein causes Creutzfeldt-Jakob disease, the Gerstmann-Straussler syndrome, and kuru. Abnormal proteinase-resistant forms of the prion protein, which react specifically with anti-hamster prion protein antibodies, have been found in the brains of patients with Creutzfeldt-Jakob disease but not in normal brains or those of patients with Alzheimer's disease. The amyloid plaques in the brains of patients with Creutzfeldt-Jakob disease and those with the Gerstmann-Straussler syndrome react specifically with anti-hamster scrapie prion protein antibodies. Also, human chromosomes contain a single-copy prion protein gene that has been localized to chromosome 20. In addition, the amino acid sequence of the human prion protein is 90% homologous to the hamster and mouse prion protein. For these reasons, scrapie, Creutzfeldt-Jakob disease, the Gerstmann-Straussler syndrome, and kuru have been grouped under the term "prion disease."

The central pathogenic event in prion diseases appears to be the abnormal metabolism and accumulation of a normally expressed nerve cell protein. The unique feature of prion diseases is that the abnormal prion protein appears to participate in transmitting the disease. The prion hypothesis is consistent with the failure to find a virus and with the absence of an inflammatory or immune response. It is genetically consistent because although most cases of Creutzfeldt-Jakob disease are sporadic, 10% are dominantly inherited, and virtually all cases of the Gerstmann-Straussler syndrome are dominantly inherited. Furthermore, the scrapie incubation time gene is genetically linked to the prion protein gene in mice. Therefore, except for infectivity, most of the features of these diseases are difficult to reconcile with the viral hypothesis.

Prion research is now focused on determining the chemical differences between the normal and abnormal isoforms of the prion protein; whether the abnormal prion protein, either alone or with a cofactor, is the transmissible agent; and the molecular mechanisms by which prions induce disease.

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Polymerase Chain Reaction— A Novel Method for Analyzing Specific DNA Sequences

THE ANALYSIS of DNA is becoming increasingly important in the study and diagnosis of hereditary, neoplastic, and infectious diseases. Often, however, the heterogeneity or small quantity of the sample available can limit the usefulness of conventional techniques. The polymerase chain reaction is a new enzymatic method for selectively replicating a specific nucleic acid sequence up to several hundred nucleotides in length within a complex mixture to facilitate its analysis.

To use the polymerase chain reaction procedure, the DNA sequences flanking the region of interest must be known. Two short oligonucleotide primers complementary to each of the two flanking regions but on opposite DNA strands are synthesized. These primers are added in vast molar excess to the sample DNA, which is then denatured and allowed to anneal to the primers. In the presence of deoxyribonucleoside triphosphates, a thermostable form of bacterial DNA polymerase uses each oligonucleotide as a primer to synthesize a copy of the adjacent DNA strand; each newly synthesized strand then provides a new template for synthesis from the opposite primer. By repeated cycles of denaturation, annealing, and synthesis, the region between the two primers is amplified exponentially. A 220,000-fold amplification of the desired region can be achieved after 20 such cycles; the amplified sequence can then be analyzed by a variety of techniques. Automated instrumentation capable of processing many specimens for the polymerase chain reaction has recently become available.

The speed and sensitivity of the reaction procedure offer advantages for both prenatal and microbiologic diagnosis. The method has been applied to the prenatal diagnosis of sickle cell anemia and will find wider application as the genetic defects underlying other familial disorders are identified. It is also capable of detecting minute quantities of viral DNA in clinical specimens even before seroconversion occurs. The polymerase chain reaction has already proved useful in research laboratories for detecting mutations of cellular proto-oncogenes that are thought to play a role in human carcinogenesis; it may soon be used clinically to characterize these mutations in individual patients.

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Fine-Needle Aspiration Biopsy in the Diagnosis of Lymphadenopathy in Persons at Risk for AIDS

LYMPHADENOPATHY is common finding in the acquired immunodeficiency syndrome (AIDS) and in the AIDS-related complex (ARC). Although this lymphadenopathy usually has a restricted differential diagnosis, it can be difficult to establish the precise cause of the nodal enlargement by history, physical examination, radiographic studies, and laboratory tests.

At the San Francisco General Hospital and Medical Center, we have found fine-needle aspiration (FNA) biopsy to be an accurate, well-tolerated, cost-effective, and useful method to initially evaluate lymphadenopathy in patients with AIDS or ARC. We have done more than 120 FNA biopsies of lymph nodes in such patients.

In our experience, about half the lymph node biopsy specimens in such patients show lymphoid hyperplasia. The other half reveal non-Hodgkin's lymphoma, mycobacterial infection, Kaposi's sarcoma, Hodgkin's disease, and various metastatic tumors. The smears showing lymphoid hyperplasia are characterized by a pleomorphic population of lymphocytes, histiocytes, polymorphonuclear leukocytes, plasma cells, and other lymphoid elements. The smears showing non-Hodgkin's lymphoma are characterized by a monomorphic population of abnormal lymphoid cells; we have further classified these cases as diffuse large cell, large cell immunoblastic, and small noncleaved lymphomas. The smears of patients with mycobacterial infections have consisted of histiocytes with thousands of intracytoplasmic organisms. The smears showing Kaposi's sarcoma have clusters of bland spindle cells not associated with inflammatory elements.

Falsely abnormal results ("false-positives") of FNA biopsies of lymph nodes in this group of patients did not occur in our series, but falsely normal ("false-negatives") results can occur. Possible reasons for false-negative results include sampling errors in lymph nodes with focal disease, taking a biopsy of a benign lymph node in a patient with abnormal nodes elsewhere, and error in microscopic interpretation. Because false-negative FNA biopsies can occur, it is imperative that clinicians using this test realize that a benign result does not entirely rule out involvement of the lymph node by a malignant or infectious process.

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DNA Fingerprinting—Applications for Resolving Medical, Legal, and Criminal Issues

THERE is now a genetic test to determine individual identity. This DNA test or "DNA fingerprinting" holds the same standard of certainty as a set of fingerprints. The test exploits the occurrence of tandem-repetitive regions of DNA—minisatellites—which are scattered throughout the human genome. The minisatellites are highly polymorphic or hypervariable, resulting from unequal exchanges that vary the number of short repeat units in a minisatellite. Researchers at Leicester University, England, isolated three human minisatellite DNA fragments by molecular cloning, each containing tandem repeats of closely related variants of a short consensus sequence. Using these cloned DNA fragments as probes to detect the homologous sequences in the restriction endonuclease-digested human DNA, they discovered DNA banding patterns ("fingerprints") that are completely specific to each person. The estimated frequency of unrelated persons showing the same DNA fingerprint is extremely low— 5×10^{-19} —and for siblings to share the same pattern is only 1×10^{-6} .

The possible applications of this test to various fields are immense. It opens up a novel approach in forensic science: bits of tissue, stains of blood, or other body fluids left at the scene of a crime may be used to identify their human source. The test has already been done by the Leicestershire police to identify a murderer in a group of several thousand suspects. A miniscule specimen is sufficient to yield a few micrograms of DNA, material whose stability confers an additional advantage for its use as a marker for identification. The state of California is planning a computerized data bank of DNA fingerprinting information on convicted criminals to facilitate the rapid identification of repeat offenders. The test is also conclusive for all practical purposes in resolving cases of controversial parenthood or other familial relationships. Recently, an immigration case concerning questionable maternity was settled by DNA fingerprinting, permitting the son's emigration to England. Routine DNA fingerprinting by immigration authorities should accelerate the application process and avoid cases of arbitrary judgment by immigration officials.

The test provides an unequivocal criterion for discrim-

inating between monozygotic and dizygotic twins of the same sex at birth, until now a problematic area in genetic studies involving human twins. Other potential medical applications of the test include monitoring engraftment of donor marrow; ascertaining the source of clinical specimens in cases of mix-up; and, perhaps eventually, with an expanded range of minisatellite probes or appropriately synthesized oligonucleotide probes, examining genetic predispositions for diseases for which suitable markers are lacking.

With dramatic success already shown, there is a growing commercial interest in the test, and, in fact, the Imperial Chemical Industry has opened in the United Kingdom its first laboratory for DNA fingerprinting.

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Lymphocyte Gene Rearrangement Studies in Formalin-Fixed, Paraffin-Embedded Pathology Specimens

THE use of recombinant DNA technologies to detect clonal rearrangements of immunoglobulin or T-cell receptor genes is becoming an increasingly valuable adjunct to more conventional methods in the diagnosis and assessment of B- or T-cell lymphoproliferative disorders. Until recently this technique depended on the availability of fresh or frozen tissue specimens, limiting its applicability in clinical medicine. We have therefore examined the feasibility of using our previously reported procedure for extracting DNA from formalin-fixed pathology specimens for gene rearrangement studies in such specimens.

We were able to show clonal rearrangement of heavy and light chain immunoglobulin genes in about 75% of blocks of formalin-fixed, paraffin-embedded B-cell lymphoma specimens retrieved from the pathology archives at our institution. The success rate at recovering intact high-molecular-weight DNA varied substantially depending on the hospital center from which the paraffin blocks were obtained. The most common reason for failing to recover high-molecular-weight DNA was the use of suboptimally fixed tissue containing partially autolysed areas. Overfixed material was also unsuitable because the amount of intact DNA recovered decreased with the

increasing time of exposure to fixative. Tissues immersed in mercuric chloride-containing fixatives such as Zenker's or B5 were not suitable for gene rearrangement studies.

The best results will, therefore, be obtained with tissues sectioned and fixed in buffered formalin immediately after the surgical procedure and preferably for a period of no longer than 24 hours before being embedded in paraffin. Tissues fixed for as long as five days may still be usable, but the quantities of material recovered would be much smaller. Despite its limitations, this technique increased considerably the number of specimens amenable for gene rearrangement studies and should make this approach more applicable to the clinical evaluation of lymphoproliferative disorders.

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Neuropathology of AIDS Dementia

THE AIDS Dementia Complex (ADC) was recognized two to three years ago as a syndrome of progressive neurologic dysfunction that occurs in a substantial proportion of patients with the acquired immunodeficiency syndrome (AIDS). Patients with AIDS may have neurologic abnormalities as a result of one or more of several types of neuropathologic disorders, including opportunistic infections caused by viruses—such as cytomegalovirus, papovavirus, Herpes simplex and zoster viruses—*Toxoplasma gondii*, and fungi such as *Cryptococcus neoformans*, lymphoproliferative disorders including lymphoma and lymphomatoid granulomatosis, and vascular or anoxic-ischemic lesions. Peripheral neuropathy is also frequently found. Early in the AIDS epidemic, however, it became clear that cerebral dysfunction developed in some patients in the absence of any of these specific causal factors. Instead, postmortem examination of the patients' brains revealed poorly defined inflammatory lesions including scattered microglial nodules and perivascular lymphocytes, and myelin loss with intense astrogliosis within white matter of the centrum semiovale of the cerebral hemispheres. Furthermore, Southern blotting methods, in situ hybridization, immunocytochemistry, and electron microscopy showed the presence of the human immunodeficiency virus (HIV) in the brains of many of these patients. A small but definite subset of patients seropositive for HIV appeared to have "pure" brain involvement by this disease without peripheral or systemic manifestations of the syndrome, apparently reflecting neurotropism of HIV in these patients.

Though the ADC is now a recognized and reasonably defined clinicopathologic disorder, its nosology is by no means clear. Patients with the ADC often appear demented out of proportion to the amount of structural damage in the nervous system, although the observed dementia corresponds to the subcortical type expected in patients with primarily white matter brain damage. Conversely, evidence of HIV infection of brain is seen in neurologically normal patients. Although HIV forms with tropism for the nervous system have emerged, the cell type in the brain most commonly infected by HIV is one with macrophage or microglial markers. Infection of astrocytes has been recorded in a few cases, and there is little evidence for infection of neurons or oligodendrocytes. One hypothesis is that HIV-infected macrophages release a product or toxin that damages adjacent white matter.

The pathologic diagnosis of ADC due to HIV infection of brain is based on fairly subtle criteria. White matter injury may be inconspicuous unless large myelin-stained sections are carefully examined. Astrogliosis is best determined using an immunocytochemical procedure for glial fibrillary acidic protein. Finally, perivascular multinucleated cells—including giant cells—with foamy or granular cytoplasm are generally accepted as a marker for HIV within the nervous system. Commercially available antibodies and probes for HIV can also be used for immunocytochemistry or in situ hybridization. The diagnosis can even be made on brain biopsy, but this must be done with great caution because similar, though not identical, white matter changes without the presence of multinucleated cells may be seen in cases of progressive multifocal leukoencephalopathy or in reactive brain tissue around a lymphoma or other infectious process.

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Papillomavirus in the Lower Female Genital Tract

HUMAN Papillomaviruses (HPV) are classified as genotypes, using molecular hybridization techniques to determine DNA composition, rather than as serotypes based on structural antigens; each genotype has less than 50% genome homology with the other

types. At least 46 types of HPV have been identified, 12 of which are associated with lesions of the female genital tract.

Morphologically, condylomas and cervical and vulvar intraepithelial neoplasia may show koilocytotic atypia; this koilocytosis is associated with the presence of HPV. Virus particles have been found in condylomas by electron microscopy, and immunohistochemistry has localized HPV structural antigens to the nuclei of koilocytes.

A number of hybridization techniques may be used to assess tissues for HPV. Southern blot hybridization, applicable to freshly obtained cells and tissues, is the most sensitive and specific techniques and can detect less than one copy of HPV genome per cell. Under high and low stringent assay conditions to vary the closeness of the nucleic acid hybrid match, HPV of known and unspecified types can be detected. Dot blot hybridization is a faster but less specific method. In situ filter hybridization was developed for use with freshly exfoliated cells; it also yields more false-positives than the Southern blot technique. In situ tissue hybridization on paraffin-embedded tissue permits specific HPV-infected cells to be identified and localized. With autographic detection using sulfur 35 or tritium, the sensitivity and specificity are similar to those of Southern blotting; with a biotin label, the sensitivity decreases.

Overall, the Southern blot technique has detected HPV DNA in 80% to 90% of cervical condylomas and intraepithelial neoplasia and in 70% to 95% of invasive cervical carcinomas. Differences exist among HPV genotypes in their distribution in the genital tract and in the severity of their associated lesions. In one study, 54% of cervical biopsy specimens of condyloma and intraepithelial neoplasia grade I were associated with HPV type 6 or 11, 13% with type 16, 18, or 31, and 12% with unspecified types; in 21% no HPV was detectable. In contrast, 68% of biopsy specimens of cervical intraepithelial neoplasia grades II and III were positive for type 16, 18, or 31, 12% for type 6 or 11, and 12% for unspecified types, with no HPV detectable in 8%. Other authors have reported comparable trends.

Thus, HPV types 6 and 11 are generally found in ordinary condylomas, although they have infrequently been identified in squamous carcinomas, predominantly of verrucous pattern. Type 16, 18, 31, 33, 35, and 45 are considered to be of higher oncogenic potential and are found mainly in atypical condylomas, moderate and severe dysplasias, and carcinoma in situ and invasive carcinoma of the cervix and vulva. HPV 16 is the most common HPV type identified in invasive cervical squamous cell carcinoma, while type 18 shows a greater association with adenocarcinoma and adenosquamous carcinoma. Preliminary evidence suggests that a progression from condyloma or cervical intraepithelial neoplasia grade I to cervical intraepithelial neoplasia grade III is associated with type 16 or 18 or a mixed infection including one of these types. More than one HPV type

are detected in 10% to 20% of patients with carcinoma in situ. Various HPV genotypes, including types 16 and 18, have been detected in 11% of women with normal smears from cervical screening.

There are differences in the physical state of the viral DNA in benign and malignant lesions. Viral DNA is present as extrachromosomal episomes in most preinvasive lesions. Integrated HPV DNA has been noted in dysplasias, invasive carcinomas, their metastases, and cell lines derived from cervical carcinomas.

These findings show important differences among HPV genotypes and strongly suggest that some types of HPV may play a role in carcinogenesis in the lower female genital tract.

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Using the Polymerase Chain Reaction in Detecting Infectious Agents

THE diagnosis of infectious diseases is an important function of pathologists. Because most microorganisms are difficult or impossible to detect or because they speciate on histologic examination, a definitive diagnosis usually depends on culturing. This, however, can be an expensive and time-consuming process, and methods for culturing certain microorganisms are not available. Furthermore, fresh tissue is needed.

In 1985 a new technique of DNA amplification, known as the polymerase chain reaction, was described. With this method, any DNA fragment of known sequence can be selectively amplified and subsequently determined by either dot or liquid hybridization. The DNA does not have to be purified and can even be directly obtained from deparaffinized, thick sections of formalin-fixed, paraffin-embedded material. Therefore, the presence of any infectious agent in tissue or body fluid can be established with sensitivity and specificity, provided that a portion of its DNA sequence is known. This method has been successfully applied to the identification of the human immunodeficiency virus in blood and the human papillomavirus in cervical carcinoma specimens.

The method as described above, however, still involves hybridization using probes labeled with phosphorus 32; therefore, it is not suitable for routine clinical use. Recently the procedure has been improved to the extent that the

amplified DNA product can be directly shown as a visible band on an agarose gel after electrophoresis and staining with ethidium bromide. We have successfully used this protocol to identify hepatitis B virus in serum specimens and herpes-virus in paraffin blocks of specimens of infected skin, with 100% sensitivity and specificity. With this modified technique, the entire procedure can be done in less than six hours, with no need for radioisotopes. Therefore, the polymerase chain reaction offers a rapid, sensitive, and specific technique for detecting infectious agents that can use both fresh and fixed material and in the future may be increasingly used in clinical laboratories for diagnostic purposes.

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Diagnosis of Small Round Cell Tumors in Children

THE term "small, round, blue cell tumors" refers collectively to a group of several aggressive malignant disorders of childhood of diverse histogenesis that are capable of presenting histologically as proliferations of small primitive cells with round nuclei and undifferentiated cytoplasm. The most important of these are lymphoma, Ewing's sarcoma, rhabdomyosarcoma, and neuroblastoma, although a number of other disorders are occasionally considered in the differential. While most cases of each of these neoplasms can be diagnosed by conventional histopathology, some of these tumors elude identification by routine light microscopy alone. Fortunately, several ancillary techniques, including sophisticated applications of recent advantages in immunology, genetics, and molecular biology, are available for resolving problematic cases.

Electron microscopy will often provide an answer in these cases by revealing neuritic processes in neuroblastoma, actin-myosin bundles in rhabdomyosarcoma, glycogen pools and a general lack of cytoplasmic differentiation in Ewing's sarcoma, an absence of true cell attachments in lymphoma, and various other features. Immunocytochemistry has proved its value in the diagnosis of small, round, blue cell tumors. The detection of myoglobin or desmin or both in primitive tumor cells may confirm the diagnosis of rhabdomyosarcoma, while a positive reaction for neuron-specific enolase may point towards neuroblastoma or other primitive neural tumors.

Newer monoclonal antibodies against muscle-specific actin and various neural antigens such as Leu-7 and HSAN 1.2 are providing additional help. The demonstration of leukocyte-common antigen may be invaluable in the diagnosis of lymphoma in an unusual site, while a battery of more specific markers may aid in its precise classification.

The most exciting recent advances in the diagnosis of small, round, blue cell tumors have been in the study of tumor cell chromosomes and DNA by cytogenetic and molecular genetic methods. Specific chromosomal abnormalities have been found in certain tumors, such as reciprocal 11:22 translocation in Ewing's sarcoma. The finding of the same translocation in peripheral neuroepithelioma raises fascinating histogenetic possibilities. Studies of oncogene amplification and expression in small, round, blue cell tumors, such as the N-myc onco-

gene in neuroblastoma, have been shown to provide useful diagnostic and prognostic information and to shed light on tumorigenesis. These and other newer developments bring us closer to our goal of a precise diagnosis in every case of small, round, blue cell tumor.

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The World's Longest Insulin Patient

LEROY H. WARDNER, M.D.

WHEN Dr. Morton Ryder, a 1918 graduate of Cornell University Medical College, journeyed to Toronto early in June 1922 to see Dr. Frederick Banting, the survival of his young diabetic nephew was much in doubt. Weighing 26 pounds, five-year-old Teddy Ryder had been kept alive for almost two years through a near-starvation diet, the only life-prolonging treatment for diabetes then known. Teddy had seemed so close to death the previous December that his family had not bought a Christmas tree, fearing the boy would not last until Christmas Day. Somehow he did survive, though, and in February 1922 a newspaper report from Toronto broke the electrifying news of the experiments of Banting and Charles Best with insulin. Dr. Ryder quickly wrote to Banting, but then, unaccountably, the knack of making the pancreatic extract was lost, not to be regained until the end of May. A little over a week later Dr. Ryder set out for Toronto to plead his nephew's case directly to Dr. Banting.

Today, thanks to his uncle's intervention, Ted Ryder lives comfortably in his West Hartford, Connecticut, apartment, having taken insulin longer than anyone else in the world. He is 71 years old.

Teddy had been a normal, healthy child until he was four. "At that time," his late mother, Mildred, recalled in an interview with *The Toronto Star* in 1983, "he was growing tall, but he wasn't putting on any weight. And he couldn't get enough to eat." It was the Ryders' family physician in Keyport, New Jersey, who diagnosed diabetes. Dr. Ryder, then interning at Bellevue, hurried out that night to the family, but the news he had for his brother and sister-in-law was no comfort: within a short time, he told them, their young son would probably be dead.

The Ryders refused to give up hope for Teddy, slim though his chances for survival might be. Looking to prolong his life by any means possible, they took him to a

physiatric institute in Morristown, New Jersey, run by Dr. Frederick Allen, an eminent diabetologist known for his brusque manner and extremely restrictive diets. After his first meal at the institute, the four-year-old patient commented, "Mama, they don't know how to feed little boys here." Years later he would recall, "They'd give you cabbage; they'd cook this stuff three times, they'd throw out the juice and with it most of the flavor. So you had this sort of colorless, tasteless roughage, and I guess you thought you'd eaten after you finished it." Existing on a diet of jellies and washed bran cookies in addition to the thrice-cooked cabbage, Teddy began a scrapbook in which he put pictures of food he had cut out of magazines.

On his visit to Toronto early in June, Morton Ryder was told by Banting to bring Teddy for treatment in September. The young physician replied that his nephew would not be alive by then. Returning to New York with the hope that treatment could be arranged earlier, Dr. Ryder wrote a long letter to Banting on June 25 seeking a commitment for early treatment and laying out in detail his nephew's medical history. Because the letter so well illustrates what an all-but-impossible struggle the treatment of diabetes once was, I will quote it virtually in its entirety.

In accordance with our conversation of June 1st, in Toronto, I am writing to learn whether, as you then anticipated, you will be able to treat my little nephew by about July 1st.

The family would be unable to continue treatment indefinitely, should the expense of preparation of the extract continue to be as high as the figure you then mentioned, but, if it is likely to be more reasonable within a few months, they will gladly pay whatever is necessary at the present time. It seems to be pretty clear that we must not delay if the boy's life is to be saved. (Perhaps you have a better idea now of what the expense is likely to be by the end of the summer.)

If you are able to take him, the mother will come with him and stay in Toronto as long as you consider it necessary for him to be there. You

LEROY H. WARDNER, M.D., practiced obstetrics and gynecology as a staff member of Hartford Hospital and has been retired since 1983.

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mentioned something like two months.

I am sending an outline of the case that you may have a better idea of it. As I told you, his diabetes has been rigidly controlled, to the extent not merely of keeping the urine sugar-free and practically acetone-free, but to the extent of keeping the blood sugar constantly normal, regardless of weight, strength, and so on. This has been done in the firm belief that it is the means of prolonging life as far as possible, and this we have wanted to do, in the hope of just such a cure as you have developed. He has now lived a year and eight months since diabetes was discovered, at the age of four. He has been under the care of Dr. F. M. Allen (for the first year) and Dr. H. O. Mosenthal, and quite thoroughly studied, so that a cure, in your hands, will mean a good deal.

Briefly, the history is as follows. (In the event of your accepting him, we can send you his record in detail, day by day, with a complete account of his diet, and all his laboratory findings.)

Theodore Ryder, 5 years, 9 months.

Family history: Both parents well. No diabetes. One sister (2 years) well. Grandparents: no diabetes—three living and well. Great-grandparents: two had diabetes in old age.

Personal history: Normal birth. Breast-fed. No exanthems. Weight normal till 3 years old—no gain after that. No serious illnesses, no serious accidents. Nocturnal enuresis began suddenly September 1920.

Diabetic history: Discovered by family physician, November 1, 1920 (age 4 years, 2 months). At this time had polyuria, polydipsia and polyphagia (the last slight and of about two weeks duration). Dry skin and lips, slightly flushed cheeks. Mentality normal.

November 1-19, 1920: Regular diet. Treated by family physician by oxygen inhalations and rectal injections of oxygen; 24-hour specimens of urine on the 17th and 18th contained 90 and 120 grams of glucose, about two thirds of the weight of carbohydrate ingested in the food.

November 19-December 3, 1920: Treated at Dr. F. M. Allen's sanatorium at Morristown, New Jersey. Put on a diet of protein/30, carbohydrate/10. Became sugar-free and had a normal blood within 24 hours. Diet gradually increased, controlled by frequent blood-sugar determinations. Discharged with normal blood sugar on diet of protein/45, fat/62, carbo/15—800 calories. The diet was accurately weighed out at home and regulated by blood-sugar determinations every two weeks at Morristown.

March 1, 1921: Apparently in equilibrium on protein/50, fat/66, carbo/20—900 calories. In-

crease to 1,000 calories regularly caused hyperglycemia.

May 10-22, 1921: At Dr. Allen's again for re-determination of tolerance (Dr. A. believed patient had broken diet). Discharged with normal blood sugar on protein/40, fat/64, carbo/15—800 calories.

July 31, 1921: Has hyperglycemia on protein/35, fat/58, carbo/10—700 calories.

September 12, 1921: Hyperglycemia (155) on protein/25, fat/31, carbo/5—400 calories.

September 13, 1921: Put under care of Dr. H. O. Mosenthal, of New York. The change was made because we wished to allow an increase of diet that would cause hyperglycemia, though not glycosuria—and Dr. Allen could not be persuaded to adopt such a compromise.

September 13: Protein/30, fat/60, carbo/10—700 calories.

October 12, 1921: Has had no glycosuria. Blood sugar determinations were not made. Diet increased to protein/34, fat/64, carbo/10—750 calories.

October 17, 1921: Glycosuria (first since treatment began, November 19, 1920).

October 17-December 10, 1921. Diet varied from 400 to 750 calories, exclusive of fast days. Various combinations were tried There was frequent glycosuria and acetonuria; blood-sugar determinations not made. The patient did not feel at all well during this period.

December 10, 1921: Went back to strict 'Allen regime,' under care of Dr. M. Ryder. The diet has been gradually increased from protein/20, fat/15, carbo/0, calories 224 to protein/20, fat/36, carbo/5, calories 425. The blood sugar fell to normal, and has remained so. There has been no ketonuria and no glycosuria except for one day on each of two occasions, when the diet was raised somewhat above the last figures.

During the period from December 10-June 24, under strict control of the diabetes, patient lost about four pounds (from 30 to 26). He has, however, felt invariably well and has been about the house continually, with no illness save for occasional transient constipation. This has been met by frequent colon irrigations. Agar-agar jellies, washed bran cookies, broth, and thrice-boiled vegetables have been used rather extensively to appease hunger, though they have been curtailed as much as possible to avoid too great distension of the abdomen.

The urine contained a trace of acetone (nitroprusside reaction) constantly for the first year of treatment, but during the last six months there has been none, although the fat/glucose ratio has for some time been 2.1.



Dr. Morton Ryder (top left) in 1922, the year he wrote Banting on behalf of his nephew, and Dr. Maurice Root (top right) as a medical student. Below, classmates Ryder and Root (front row left and right respectively) as members of a student club at Cornell University Medical College in 1915.

For a time, sodium hydrogen carbonate was given in small doses, not to combat the trivial acidosis but to allow water retention and so prevent too great loss of weight. Recently no soda has been used, but the patient is allowed generous rations of table salt, with the same end in view.

He is now, as you will judge from the weight (26 pounds), very considerably emaciated. He walks about the house, though to look at his legs one would suppose him unable even to stand. He can be interested in numerous diversions, but for months has not had the energy to play by himself.

Occasionally he is very irritable, and rarely almost unmanageable. It looks to me as though a very few more months on this starvation diet will be all he can hold out—and we are very sure that any increase of diet would shorten his existence.

I need not tell you how earnestly I hope that you will see your way clear to treat him. We will try to pay whatever fee you consider due yourself: it would be very unfair for you to charge only the expense of preparation of the extract, as you spoke of doing.

Hoping for an early consideration of the case, I am, yours sincerely, Morton Ryder.

The Ryders had their answer in a letter dated June 28:

Your letter of June 25th is received. I have made plans to commence treatment of your nephew about the first of July or any time after that date. Extract is still difficult to obtain, but we are doing our best. Yours sincerely, F. G. Banting.

Teddy and Mildred Ryder arrived in Toronto by train on July 8. Being too weak to walk, Teddy had to be carried almost everywhere by his mother. For the first two days in Toronto, no insulin was available, the remainder of the last batch having gone bad. But on Monday, July 10, 1922, Teddy Ryder received his first insulin injection and stopped dying. Years later Ted expressed regret at not being able to remember who gave him his first shot, but it was Banting himself who usually came to the room that the Ryders had rented, bringing the precious vials of insulin and giving Teddy his injections. "Sometimes he had to have three or four injections a day," Mildred Ryder recalled in 1983. "Dr. Banting would say, 'Well, we tried this on a rabbit, and we'd better go easy on this lot—it may be too strong.' But if there was any little sign of Teddy's having a reaction, he would come running."

Banting, she added, would sometimes drop by in the evening to talk. "He would tell about his troubles with a particular young lady. He'd asked her a dozen times to marry him in the past and he'd always been refused. Now she wanted to come back, and he didn't know what to do."

Banting, she said, would also expound at length about Professor J. J. R. Macleod, who had reluctantly given



Ted Ryder, now 71 years old. A patient of Dr. Maurice Root for over 50 years, he is now in the care of Dr. David Wilcox '55.

Banting laboratory space, but who now seemed determined to take credit for the discovery.

Banting was like a favorite uncle to the small group of patients he agreed to treat that summer, taking them for rides in the country in his new car or dressing up in costume for one of their birthday parties. On one occasion he took Teddy and his mother on a tour of the laboratory at the University of Toronto where he and Best had slept alongside the dogs they used in their experiments and where they would cook their food over bunsen burners while the experiments progressed.

Years later Mrs. Ryder could recall no single moment when she realized Teddy was going to live, but he was filling out steadily. By the time the Ryders returned to New Jersey in early October, the change in the little boy was dramatic. Morton Ryder, who had not seen Teddy in months, wrote to Banting, "I cannot tell you too strongly how much I am pleased with what you have accomplished." Teddy wrote to his hero in Toronto as follows:

Dear Dr. Banting, I wish you could come and see me. I am a fat boy now and I feel fine. I can climb a tree. Margaret (Teddy's sister) would like to see you. Lots of love from Teddy Ryder.

When Banting addressed a packed hall of physicians in New Jersey the following January, he had Teddy, now a chubby little boy, come up and sit on his knee.

In 1929, the Ryders revisited Toronto, where Teddy's grandfather, who had paid much of the cost of his treatment, attended a bankers' conference. On that occasion the Ryders took what was probably the earliest movie of Banting working in his laboratory.

Ted Ryder's life since insulin has had a reassuringly normal course. In 1925 his family moved to Hartford,

Connecticut, where his father, an engineer, became one of the first employees of Pratt & Whitney, the manufacturer of aircraft engines. Ted attended Trinity College in Hartford before receiving a degree in History from Cornell, the alma mater of three generations of the Ryder family. It was the first time he had been far from the protective care of his mother.

Since Ted's graduation from Cornell in 1942, he has had a varied career. He has worked as a librarian, cartographer, and bookseller, traveling to areas as remote as James Bay, Canada. To his regret, he has been a life-long bachelor. "It's lonesome," he lamented in a 1983 interview. "It's frustrating not to have a companion and to be mothered."

Ted Ryder's good health and longevity are particularly notable because of the lack of consistency in the quality and potency of early insulin injections. Undoubtedly much of the credit for his continued health must go to another Cornell graduate and friend of his uncle's, Maurice (Tim) Root '18, who was Ted's physician for over 50 years. Dr. Root, an alert 96, now lives in Rockland, Maine.

Ted has been cared for by David S. Wilcox, CUMC '55, since 1981, during which time he has had four hospitalizations. Initially he was admitted to change his insulin program to regular and protamine zinc, and he

was later changed to NPH alone. His only manifest complication was neuropathy.

On three occasions he has required amputation of a single toe as a result of gangrene and localized infection in association with his neuropathy. At each admission he has had a normal ECG, normal BUN and creatinine, and no other complications of his 67 years of diabetes. He has retained good vision and good cardiac and renal function and continues active and independent.

Morton Ryder practiced internal medicine with distinction for many years in Rye, New York, serving for 24 years as chief of the medical staff at United Hospital in Port Chester. Dr. Ryder retired in 1966, and died in 1980 at the age of 85.

Mildred Ryder lived to the age of 93. She was my patient, and right to the end retained the vigor, strong will, and solicitude for her son that had saved his life decades earlier. "We were lucky," she told a reporter not long before she died. "We had Uncle Morton to back us up. I look on it as Dr. Banting's miracle. We have lived through remarkable times."

This article was made possible by the keen interest and cooperation of members of the Ryder family and of Michael Bliss, professor of history at the University of Toronto, who furnished excerpts, photographs, and information from the Sir Frederick Banting Archives. Professor Bliss' *Banting, a Biography* was published in Canada in 1984.

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The Future of Family Practice

Implications of the Changing Environment of Medicine

AMA COUNCIL ON LONG RANGE PLANNING AND DEVELOPMENT

THE Council on Long Range Planning and Development of the American Medical Association (AMA) has been studying trends in the environment of medicine and assessing the impact of these trends on health care delivery.¹ The Council realizes that each medical specialty has unique characteristics and will respond differently to the anticipated changes in the environment of medicine. This report, part of a continuing series prepared by the Council, focuses on the specialty of family practice.

Background

Family practice is characterized by an orientation away from increased segmentation of patient care and toward a model in which the physician provides a wide assortment of medical care for the patient from the prenatal period to death. This specialty had its roots in general practice, and a number of factors contributed to its inception.

In 1940, three of every four physicians in patient care were general practitioners. With WW II the age of specialization began to flourish, which brought a rapidly changing medical environment. By 1949, general practitioners represented two out of three physicians in patient care, but their practices were changing. While they were striving for hospital privileges on the basis of proved capability, specialty-oriented hospital medical staffs were establishing requirements that frequently included board certification. In addition to restriction of hospital privileges, general practice residency training was extremely limited. As the board-certified specialists gained stature,

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the status of the general practitioner diminished. These challenges prompted a series of actions by general practitioners not only to survive but to strengthen and improve their position in American medicine.²

Their initial steps were to provide a basis and united voice for their concerns and objectives. The year 1946 marked the first meeting of the Section on General Practice of the AMA, and 1947 saw the formation of an organization to specifically represent general practitioners, the American Academy of General Practice (AAGP). In 1957, the AMA established a joint committee, with representatives from its Council on Medical Education and Section on General Practice as well as the Association of American Medical Colleges (AAMC) and the AAGP, to "objectively analyze and make recommendations as to the best background preparation today for general practice."² The final report of the Committee on Preparation for General Practice of the AMA (adopted by the AMA House of Delegates in 1959) stressed the physician's interaction with the patient and family, established the terms *family practice* and *family physician*, and proposed the development of new graduate education programs for family practice.³

In addition to these actions by the medical profession, the public and government agencies became involved. Four special commissions working independently and with varying agendas issued reports calling for increasing the number of family physicians and changes in medical education. One of these, the Report of the Ad Hoc Committee on Education for Family Practice, "Meeting the Challenge of Family Practice" (adopted by the AMA in 1966), greatly contributed to subsequent efforts to develop essentials for family practice residency programs and to obtain approval for a certifying board.⁴

This report was prepared by representatives from the Council on Medical Education and the Section on General Practice of the AMA, the AAMC, and the AAGP (changed in 1971 to the American Academy of Family Physicians [AAFP]). Its several recommendations in-

cluded the following: that the recognition and status accorded to family practice should equal that of other medical specialties, that incentives should be developed for medical students and young physicians to enter this specialty, and that funds should be allocated to support family practice teaching programs and research in patient care and community medicine.⁴ These issues, which continue to be of interest and concern to the specialty of family practice, are addressed later herein.

Table 1
Data for Federal and Nonfederal Physicians*

<i>All Physicians, No. (%)</i>			
<i>Year</i>	<i>Total</i>	<i>Women</i>	<i>Foreign Medical Graduates</i>
1970	334,028 (100)	25,401 (7.7)	57,217 (17.1)
1975	393,742 (100)	35,636 (9.1)	80,848 (20.5)
1980	167,679 (100)	54,284 (11.6)	97,726 (20.9)
1983	519,546 (100)	69,588 (13.4)	112,005 (21.6)
1986	569,160 (100)	86,670 (15.2)	123,090 (21.6)

<i>Family Practice Physicians, No. (%)</i>			
<i>Year</i>	<i>Total</i>	<i>Women</i>	<i>Foreign Medical Graduates</i>
1970	57,948 (100)	2,486 (4.3)	6,742 (11.6)
1975	54,557 (100)	2,866 (5.2)	7,757 (14.2)
1980	60,049 (100)	4,677 (7.8)	9,162 (15.2)
1983	64,154 (100)	6,706 (10.4)	11,184 (17.4)
1986	67,687 (100)	8,724 (12.9)	12,589 (18.6)

*From Roback and colleagues: *Physician Characteristics and Distribution in the U.S.*⁵

In 1969, the American Board of Family Practice (ABFP) was established as the 20th primary certifying board in American medicine. Two elements in this certifying board's requirements were unique: (1) a "practice-eligible" route to sit for the certification examination and (2) a provision for mandatory recertification every six years to maintain ABFP diplomate status.

Explicit identification of the specialty of family practice and the physicians practicing this specialty was then reviewed and refined. The following definition of family physicians was officially endorsed by the AAFP Congress of Delegates in 1975:

The family physician provides health care in the discipline of family practice. His/her training and experience qualify him/her to practice in the several fields of medicine and surgery. The family physician is educated and trained to develop and bring to bear in practice unique attitudes and skills which qualify him or her to provide continuing, comprehensive health maintenance and medical care to the entire family regardless of sex, age or type of problem, be it biological, behavioral or social. This physician serves as the patient's or family's advocate in all health-related matters, including the appropriate use of consultants and community resources.

**Current Socioeconomic Indicators
Relevant to Family Practice**

To provide a context for the issues affecting the specialty, this section will review the demographic trends and socioeconomic indicators of family practice. Data from the AMA Physician Masterfile⁵ reveal that over a 21-year period (1965-1986) the number of US family physicians (including general practitioners) in both federal and nonfederal practice declined to a low in 1975 and gradually increased through 1986 (Table 1). From a total family physician count of 54,557 in 1975, the

number of physicians in this specialty increased by 24% to 67,687 in 1986. In 1975, family physicians accounted for 13.8% of the total physician population of 393,742. Given the greater increase in the total physician population, in 1986 family physicians represented 11.9% of the physician total of 569,160. In terms of size, family practice is ranked second among all specialties (Fig 1).⁵

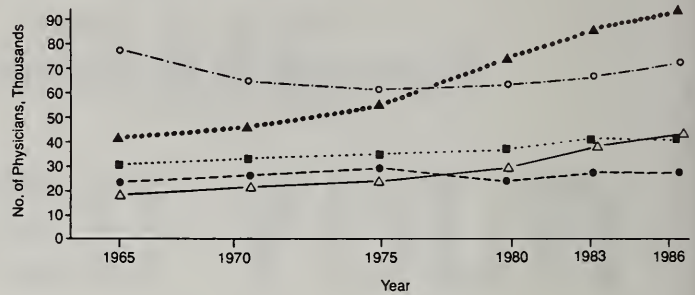


Figure 1

Trends in distribution of federal and nonfederal physicians by specialty for selected years. Open circles indicate general practice and family practice; closed triangles, internal medicine; squares, general surgery; closed circles, psychiatry; and open triangles, pediatrics (from Roback and colleagues: *Physician Characteristics and Distribution in the US*).⁵

According to the National Ambulatory Medical Care Survey,⁶ 30.5% of the 636,386,000 patient visits to office-based physicians in 1985 were to family physicians. In comparison, internists were the next highest, with 11.6% of patient visits, and 11.4% were to pediatricians, the other major providers of primary care (Table 2).⁶

Table 2
Distribution of Office Visits by Specialty, Type of Practice, and Professional Identity in 1985*

<i>Physician Specialty, Type of Practice, and Professional Identity</i>	<i>No. (%) of Visits in Thousands</i>
Specialty	
Family practice	193,995 (30.5)
Internal medicine	73,727 (11.6)
Pediatrics	72,693 (11.4)
Obstetrics and gynecology	56,642 (8.9)
Ophthalmology	40,062 (6.3)
Orthopedic surgery	31,482 (4.9)
General surgery	29,858 (4.7)
Dermatology	24,124 (3.8)
Psychiatry	17,989 (2.8)
Otorhinolaryngology	16,097 (2.5)
Urologic surgery	11,699 (1.8)
Cardiovascular disease	10,617 (1.7)
Neurology	4,992 (0.8)
All other specialties	52,408 (8.2)
Type of Practice	
Solo	323,653 (50.9)
Partnership	113,317 (17.8)
Other†	199,416 (31.3)
Professional identity	
MD	600,514 (94.4)
DO	35,872 (5.6)
Total visits	636,386 (100.0)

*From the *National Ambulatory Medical Care Survey*, cited by American Academy of Family Physicians: *Facts About Family Practice*.⁶

†Includes group practice.

In 1986, foreign medical graduates (FMGs) represented 18.6% of the total family physician population,

and women represented 12.9%. This compares with 21.6% FMGs and 15.2% women in the total physician population. Although FMGs and women constitute a smaller percentage of family physicians than physicians overall, family practice is second among all specialties in respect to the number of FMGs in the specialty and third as to the number of women.⁵

Compared with all physicians, family physicians in 1986 spent slightly more time in practice during the year (mean, 48.3 weeks per year for family physicians vs 47.5 weeks per year for all physicians). According to AMA data, family physicians devoted 57.9 mean hours per week to professional activities, of which 48.9 were in direct patient care. This practice pattern is virtually identical to that of physicians overall.⁷

Family physicians conduct more patient visits per week than physicians overall. However, patient visits for family physicians declined approximately 15% between 1976 and 1986, from an average of 163.6 per week to 139.2 per week. This mirrors the decline in weekly patient visits for physicians overall, from an average of 134.7 in 1976 to 117.7 in 1986. Patients of family physicians wait approximately 2.7 days to be scheduled for an appointment; for physicians overall, patients on average wait 6.2 days to be scheduled for an appointment.⁷

The mean fee for family physicians in 1986 for an office visit with an established patient was \$23.48. For physicians overall, the mean fees were higher on average, at \$30.10. In 1986, for physicians in the specialty of family practice, the mean net income after expenses and before taxes was \$80,300. For all physicians the mean net income was \$119,500 (Figure 2).⁷

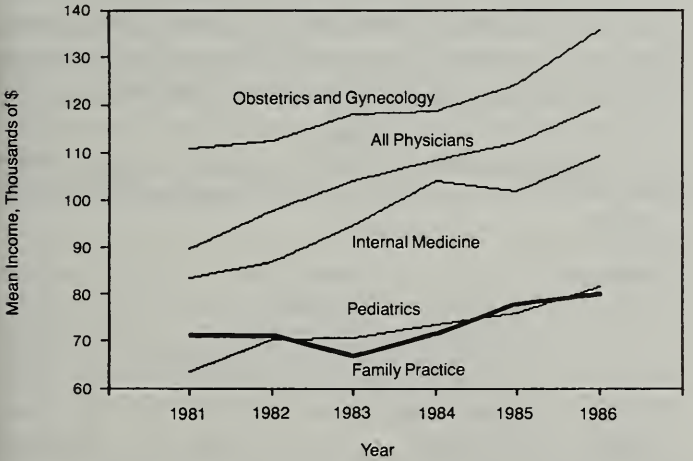


Figure 2
Mean net income of physicians after expenses and before taxes (from Gonzalez and Emmons [eds]: *Socioeconomic Characteristics of Medical Practice*, 1987).

The most common practice arrangements for family physicians are solo practice and family practice groups. Approximately 44% of all office-based family physicians who provide direct patient care are in solo practice, and roughly 27% are in family practice groups. The remainder are almost evenly divided between two-person partnerships and multispecialty groups (Table 3).⁹

Table 3
Practice Profile of Family Physicians in May 1987*

Practice Category	% of Physicians
Professional activity (majority of time) (n = 31,300)	
Administration	2.6
Direct patient care	93.5
Research	0.2
Teaching	3.3
Not reported	0.4
Direct patient care (n = 29,256)	
Alternative modes of health care delivery	
None	49.9†
Health maintenance organization	22.5
Independent practice association	12.3
Preferred provider organization	14.6
Free-standing emergency center	4.4
Hospital satellite clinic	3.7
Other	3.1
Not reported	9.2
Practice base	
Office	91.1
Hospital	6.2
Other (school, industrial, etc)	2.4
Not reported	0.3
Office-based direct patient care (n = 26,644)	
Practice arrangement	
Solo	44.3
Two-person partnership	14.5
Family practice group	26.6
Multispecialty group	13.7
Not reported	0.9
Type of income	
Fee for service	67.4
Salary plus percentage	12.2
Straight salary	17.2
Not reported	3.3

*From American Academy of Family Physicians: *Facts About Family Practice*.⁹
†Percentages do not add to 100% because some physicians are in more than one category.

Forces for Change

The Council on Long Range Planning and Development of the AMA, in consultation with the AAFP, has identified several key issues that have implications for the future of the specialty of family practice. These issues relate to professional and public image, graduate medical education, reimbursement, scope of practice, managed care, professional liability, manpower, and ethics.

Professional and Public Image

After family practice was formally established as a board-certified specialty it continued to experience some negative sentiments from within the medical profession. With the many advances that have been made in the intervening years, family practice by and large has achieved the status and influence of other medical specialties. There are occasional exceptions, however, particularly in academic centers.

The fact that family physicians provide comprehensive patient care from the prenatal period to death often puts them in direct competition in one way or another with many other specialties. Family physicians have always maintained that they refer patients to other medical specialists as appropriate. However, the perception of

some physicians in other specialties is that even the initial services provided by family physicians represent an infringement on their scope of practice. Presently, the greatest overlap and, therefore, the most opportunity for competition, comes from within the primary-care specialties of internal medicine, pediatrics, and obstetrics and gynecology.

A factor that might have initially contributed to the ambiguous status of family physicians is that their intended expertise lies in a "generalist" practice of medicine and that family practice was termed a specialty in breadth rather than depth. The development and growth of specialties from their inception through the 1960s were based on in-depth expertise in a defined body system (eg, urology), the age or gender of the patient (eg, obstetrics and gynecology), or specific types of technology (eg, nuclear medicine). The fact that family practice by its very definition does not adhere to this traditional pattern—a clearly delineated role in a specific area of expertise—gives family physicians a lesser level of influence among their medical colleagues.⁸ Before the establishment of accredited family practice residencies and the certifying board (ABFP), family physicians were viewed as having less training than their colleagues in other specialties. This perception has been largely dispelled, and family practice has taken the lead by being the first specialty board to require periodic recertification.

The lack of emphasis on a research and publication orientation for this specialty is another factor contributing to a perceived lower status within the profession. According to a 1987 AAFP Practice Profile Survey,⁹ 0.2% of the respondents identified "research" as their main professional activity, and 3.3% stated that "teaching" was their primary professional activity. In comparison, 93.5% of the physicians in this specialty listed their professional activity as "direct patient care" (Table 3).

A recent survey of graduates of the several Robert Wood Johnson Foundation Family Practice Academic Fellowship Programs shows that the research environment in departments of family practice is often far from optimal. This study concluded that only a minority of the research-trained faculty had significant time budgeted for research.¹⁰ It must be noted, however, that because family practice is a relatively new specialty, a limited number of physicians have graduated from family practice residency programs and pursued an academic career to, in turn, direct graduate medical education in this specialty. Obtaining funding for research has been and continues to be an obstacle for family practice physicians. However, a more positive environment is developing, marked by a trend toward research conducted in ambulatory-care settings.

It is likely that as this specialty becomes filled with a higher proportion of residency-trained family physicians it will continue to gain status within the medical profession. Data compiled by the AAFP show a steady growth in the number of family practice residency graduates, from 35 in 1970 to 2,359 in 1986, for a cumulative total of 21,826.⁹ In some situations, however, medical students

may lack role models in family practice, because relatively few physicians in this specialty are located in an academic setting. Furthermore, some family practice rotations are scheduled too late in the medical school program, often after students have made their specialty choice. To ensure the continued growth of this specialty, family practice will need to continue its efforts to disseminate information about its attractions to all levels of the profession, particularly medical students.

Beyond the scope of the medical profession, anecdotal information indicates that family physicians are faced with public misconceptions. There does not seem to be a widespread public understanding that family practice is a bona fide specialty. Although more and more patients are interested in having a single physician as the provider of primary care who treats the patient in the context of his or her family, there is a perception that this type of physician no longer exists. Public education campaigns, now in place, will likely contribute to an increased public awareness of the role, philosophy, and availability of family physicians and the continuity of services provided by such specialists to the patient and his or her family.¹¹

Graduate Medical Education

The emergence and rapid growth of the specialty of family practice were facilitated by federal, state, and private sector funding of residency training programs. In primarily rural and semirural states, such funding was often a direct response to strong political and legislative initiatives to address the need for more family physicians to replace the growing number of retiring general practitioners. From 49 approved residency programs in 1970 with 290 residents, the numbers increased to 388 residency programs in 1983 with 7,409 residents. In recent years the number of residency programs has declined slightly, to a total of 381 in 1986. The actual number of residents, however, has increased to 7,446.⁹ As Table 4

Table 4
Family Practice Residency Programs by Program Structure in 1987*

Program Structure Classification	Definition	No. (%) of Programs
1	Unaffiliated community hospital	35 (9.2)
2	University-affiliated community hospital	209 (55.1)
3	University-administered community hospital	57 (15.0)
4	University hospital	63 (16.6)
5	Military hospital	15 (4.1)
Total	...	379 (100.0)

*From American Academy of Family Physicians: *Facts About Family Practice*.⁹

demonstrates, just over half (55.1%) of all family practice residency programs are in community hospitals affiliated with universities.⁹ Family practice residency programs of excellent quality are frequently located in independent and/or community hospitals. One of the reasons family practice residency program directors have turned to independent and/or community hospitals for both residency training positions and patient care opportunities has been the limited availability of funding for family

practice residents in academic settings. The increasing attractiveness of family practice is likely to serve as an impetus for the further development of family practice residency programs in both the academic environment and the community hospital setting.

It is the stated goal of family practice organizations to increase the number of family physicians. The intent of some recent legislative proposals that would reduce federal funding for graduate medical education also has been to emphasize primary-care specialties, including family practice. These proposals would limit the number of years of graduate medical education to be funded by Medicare part A, "Support of Inpatient Services." Such proposals would indirectly reduce the training of subspecialists and increase the number of primary-care residency positions that could be funded.

Funding for family practice education does face two obstacles: much of the specialty is ambulatory based, and many of the services provided by family physicians are nonprocedural. Training in an ambulatory care environment is an important element in the family practice curriculum. However, graduate medical education is supported as part of the cost of inpatient care. It is difficult to allocate inpatient income to support family practice residencies. Additionally, the teaching responsibilities of the attending physicians in ambulatory centers have made it difficult for some centers to support residents primarily with income from patient fees.

In general, primary-care education in an ambulatory-care setting generates lower revenues and higher costs. A contributing element is the fact that many of the services provided by the family practice resident are nonprocedural, such as diagnosis and consultation. Nonprocedural services are currently reimbursed under the Medicare program at a lower rate than are procedural services. However, this situation is not static. Currently under development are a variety of proposed adjustments to physician reimbursement systems that have the potential to address this issue.

At the national level, the perceived need for more primary-care physicians, particularly in rural areas, might support the efforts by family physicians to secure continued funding for graduate medical education. The Consolidated Omnibus Budget Reconciliation Act (1986) established the federal Council on Graduate Medical Education (COGME), which is charged with assessing physician manpower needs on a long-term basis. In its first report to the Secretary of Health and Human Services and the Congress (July 1, 1988), COGME concluded that there is "an undersupply of physicians in family practice [Conclusion D-2]." It further identified that the "Council places the highest priority on reimbursement of residency training stipends and fringe benefit costs, training in those primary care specialties which are in short supply . . . [Recommendation 16]."¹² This may provide an opportunity for primary-care physicians, and family physicians in particular, to reaffirm their goals

and resource needs. In addition to public funding at the national level, programs that were initiated at the mandate of state legislatures and/or are funded largely by states will actively need to seek opportunities to secure continued funding.

Private foundations and voluntary health organizations will continue to be limited resources, but family practice will need to expand its funding sources for graduate medical education. In recent years an increasing percentage of family practice residency graduates have practiced in alternative health care delivery systems.⁹ Managed-care systems are generating a demand for family physicians at a rate that might create a significant shortage in this specialty. Therefore, this specialty may wish to explore the question of corporate funding for family practice residency training programs. Such funding might provide positive incentives for both the resident physician and the managed care system.

Reimbursement

Reimbursement policies of third-party payers present challenges to family physicians in obtaining acceptable compensation and assuring appropriate access to care for their patients. Because an increasing proportion of all physician gross income is derived from third-party payers, concerns generated by reimbursement systems are likely to continue for family physicians.

Respondents to a 1987 AAFP survey indicated that 37% of their patients had Medicare or Medicaid as their principal type of health insurance. The survey results also showed that over 39% of the patients were covered by other health insurance plans, including Blue Cross-Blue Shield and commercial plans, and 12% were covered under a prepayment/capitation system. The remaining 12% of family physicians' patients had no protection against health expenses.⁹

The many reimbursement mechanisms currently in use by third-party payers have had ramifications for physicians in all specialties. The reimbursement issues most problematic for family physicians are the level of compensation for office visits, counseling, and other time-intensive services; specialty differentiation; geographic differentiation; and the impact of all these factors on patient access to health care.

As discussed earlier, a long-standing issue of concern to family physicians is the disparity in reimbursement for nonprocedural vs procedural services. A related issue is the determination of the "prevailing charge" for their services under the Medicare program. The prevailing charges for family physicians were determined in 1973. Because the specialty of family practice was relatively new at that time, prevailing charges were based on the charges of general practitioners. It is the position of the AAFP that the adjusted prevailing charges currently applied to family physicians are inappropriately low and do not accurately reflect the level of services provided by these specialists.¹³

Prevailing charges are part of another issue pertinent to reimbursement, that of specialty differentiation. Some carriers base the level of reimbursement under Medicare for a particular service in part on the physician's specialty. Family physicians maintain that they are often adversely affected by this system. Family practice has joined with other primary-care specialties to call for a review of reimbursement, so that family physicians, who have the same customary charge for a service as physicians in other specialties, will be able to receive the same level of reimbursement.

Geographic differentials in third-party reimbursement have also affected family physicians. Currently, rural physicians are reimbursed at lower levels than physicians practicing in metropolitan areas. The AAFP maintains that the data do not support the popular argument that the costs of supporting a practice are substantially less in rural areas.¹³

The potential implementation of new reimbursement mechanisms will have far-reaching implications for family physicians. The development of a resource-based relative value scale is perhaps the most prominent of the proposals under consideration. The relative value scale study will assign numerical values or rankings to medical and surgical services based on variables that will include intensity, time, amortized opportunity costs of specialty training, and overhead. Primary-care physicians, especially family physicians, will be monitoring this study with interest, as it may provide them with an opportunity to address the concerns described above.

Because of the continuum of care they provide for their patients of all ages, family physicians have the potential to receive reimbursement under both Medicaid and Medicare as well as from other third-party payers. The increasing age of the US population will likely lead to more patients for family physicians who are covered under the Medicare program.

Scope of Practice

A practice profile survey conducted by the AAFP reveals that an overwhelming majority (approximately 93%) of family physicians are engaged in direct patient care. Of these physicians, fewer than half participate in alternative modes of health care delivery (Table 3). Approximately 60% of all office visits to family physicians are made by women, with the greatest number of visits from women in their childbearing years.⁹ This puts some family physicians in competition with obstetricians and gynecologists.

The aging of the US population also has implications for the future of family practice. Even though family physicians provide a continuum of care throughout the life of the patient, there will likely be a noticeable shift in their services to accommodate the health care needs of an aging population. Anticipating this trend, the ABFP and the American Board of Internal Medicine are jointly sponsoring an examination for a certificate of added qualification in the specific clinical area of geriatrics.

Another area that sometimes poses a challenge for family physicians involves obtaining hospital privileges in obstetrics and access to intensive care units. Many of these barriers are regional—urban vs rural—and reflect a direct relationship to the availability of physicians in other specialties in the same hospital. Even though some family physicians may be experiencing difficulties in obtaining a broad scope of hospital privileges at the hospital(s) of their choice, the demand for family physicians at hospitals is nationwide. According to a recent survey of all sizes of hospitals in five geographic regions (West, Midwest, Southwest, Southeast, and Northeast), family physicians are in the greatest demand. Only in the West was there a greater demand for obstetricians (20%) than for family physicians (19%). The highest demand is in the Midwest, where 40% of all responding hospitals indicated a need for family physicians.¹⁴

In many settings family physicians are in direct competition with other primary-care specialties to provide similar services. Additionally, as some medical specialties increasingly employ high technology in their patient care (eg, cardiology), this may erode the level and amount of care a family physician can provide. Conversely, increased use of technology in some specialties may elevate the complexity of the procedures performed. This could result in a shift of more routine procedures from the specialist to the primary-care physician, broadening the scope of care of the family physician.

Recent proposals have suggested combining family practice and internal medicine residency programs.^{15,16} However, such proposals are not universally supported. Eliminating the separate identities of general internal medicine and family practice would at present be unacceptable to both specialties. Nevertheless, several possibilities for cooperative efforts should be explored. A recent example of such a cooperative venture, mentioned above, was the development of a joint geriatric medicine certification process by the ABFP and the American Board of Internal Medicine. Additional opportunities for cooperative activities with other specialties include developing and obtaining funding for primary-care research, enhancing the status of primary-care academic faculty, improving reimbursement for primary-care services, and lobbying for primary-care objectives in the national political arena.¹⁷

Managed Care

Closely aligned with any discussion of scope of practice is the concept of managed care. In the traditional fee-for-service setting, this term has referred to the physician who is able to assess the health care needs of the patient and provide a broad range of medical services to address those needs. This physician served as the provider of primary care, referring the patient to different medical specialists as required. In recent years, this type of patient care has gained increased popularity in group practice settings and, particularly, in health maintenance organizations.

The dramatic increase in managed-care systems in recent years has created a strong demand for family physicians. Continuity in the provision of care, which is the hallmark of this specialty, and the ability of family physicians to treat patients of all ages make them particularly qualified to serve as case managers in managed-care systems. They are sought not only because they offer a broad range of services but also because they are perceived as cost-efficient utilizers of resources. Large multihospital and multisystem organizations have incentives to utilize resources efficiently, and family physicians might meet these needs by serving as "case managers." Managed-care systems are able to offer incentives to family physicians, such as guaranteed income, marketing the physician's services to the community, and providing office space, equipment, and personnel.¹⁸ These incentives are particularly attractive to family physicians, who in 1986 spent more than half of their gross income on practice expenses.⁷ In addition to the economic considerations, managed-care systems place additional value on disease prevention and health promotion, views strongly supported by all physicians.

In short, managed care offers new opportunities for providers of primary care, such as family physicians. It is anticipated that the continued growth of managed-care systems will result in a strong demand for family physicians. This orientation in health care delivery is likely to provide an attractive spectrum of opportunities for present and future family physicians.

Professional Liability

In 1986, self-employed family physicians paid average premiums of \$7,300 for professional liability insurance, an increase of 49.3% since 1982. As Table 5 demonstrates,

Table 5
Mean Professional Liability Premiums for Self-Employed Physicians*

Type of Physician	Mean Professional Liability Premium by Year, Thousands of \$				
	1982	1983	1984	1985	1986
All physicians	5.8	6.9	8.4	10.5	12.8
Specialty					
General practice and family practice	3.5	4.2	4.6	6.8	7.3
Internal medicine	3.7	4.5	4.9	5.8	7.1
Surgery	9.9	11.0	13.3	16.6	21.3
Pediatrics	2.9	3.9	3.4	4.7	6.3
Obstetrics and gynecology	10.8	14.0	19.0	23.5	29.3

*From Gonzalex and Emmons (eds): *Socioeconomic Characteristics of Medical Practice*, 1987.⁷

premiums paid by family physicians closely correspond to those paid by physicians in the specialties of internal medicine. In comparison, physicians overall paid an average of \$12,800 in professional liability insurance premiums in 1986—a 45.3% increase since 1982.⁷

Because family practice encompasses a wide range of health care delivery, family physicians are vulnerable to many changes in trends in claims and premium rules.

The AAFP estimates that in 1987 approximately 41% of family physicians included obstetrics in the scope of their services.⁹ This percentage represents a dramatic decline from 1985, when, according to the AAFP Active Member Practice Profile Survey, approximately 54% of family physicians included obstetric services in their practice.

The implications for both health care delivery and access are severe. Rural and underserved areas often look to primary-care physicians, particularly family physicians, for most if not all of their medical needs. The current crisis in professional liability therefore affects both the patient and the physician and, if this crisis continues unabated, the implications for patient care will be severe.

Manpower

Data on self-designated specialties collected by the AMA Physician Masterfile indicate that between 1975 and 1986 the overall active physician population increased by almost 45%.⁵ In contrast, the active family physician population, including general practitioners, grew by only 24%. During the next 15 years the AMA projects that the total physician population will increase by nearly 22%, while the number of family physicians is projected to increase by only 9%, to a total of 74,600 by the year 2000 (Fig 3).¹⁹ In comparison, the US Census

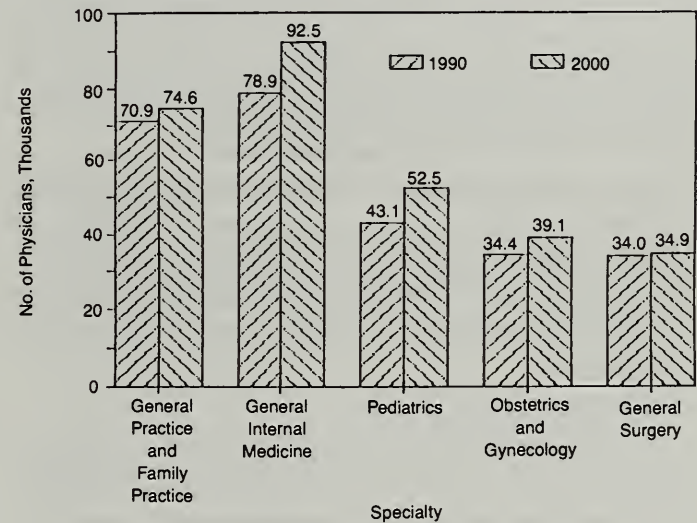


Figure 3

Projected physician population by specialty in 1990 and 2000 (from Marder and colleagues: *Physician Supply and Utilization by Specialty: Trends and Projections*¹⁹).

Bureau projects that the US population will increase by 12.3% between 1985 and 2000.¹⁹ Given these projections, it is possible that the supply of family physicians may not meet the demand for their services.

A significant characteristic of this specialty is the variance in age, particularly when this variance is correlated with the self-designation of family physician or general practitioner. In 1986, approximately 63% of all general practitioners were over the age of 55 years, and almost one third were over the age of 65 years. In contrast, in 1986, over two thirds of all family physicians were under

the age of 45 years, and approximately 36% were under 35 years of age.⁵ Between now and the turn of the century there will be further dramatic declines in the number of self-designated general practitioners and a continued concentration of family physicians in the younger age brackets.

Four factors have serious implications for the future of family practice manpower:

- There has not been a significant increase over the last few years in the number of family practice residency program graduates.
- The number of general practice physicians retiring from medicine will increase.
- Managed-care systems will increase the demand for family physicians as case managers, but as yet they have not funded or developed residency training programs to generate more family physicians to meet the demand.
- The projected growth of other primary-care specialties, such as internal medicine, pediatrics, and obstetrics and gynecology, and the projected overall surplus of physicians will increase the level of competition.

These are some of the questions that can be posed with respect to family physician manpower: Will the demand created by managed-care systems further erode the numbers of family physicians available for other types of practice? Will rural and other underserved areas continue to experience a shortage of family physicians? Will continued growth in the number of family physicians and the likelihood for increased competition among all primary-care specialties have a positive or negative effect on the environment of family practice?

There will continue to be constraints on the profession of family practice, such as those related to the scope of practice, professional liability, and others discussed earlier in this report. However, the strong demand for family physicians has positive ramifications for the future of this specialty.

Ethical and Societal Issues

Unresolved social and ethical issues will continue to shape health care delivery for all physicians. As providers of care from before birth to death, family physicians in particular have the potential to be confronted by the entire range of ethical issues facing the medical profession. It is expected, for example, that medical technology will continue to advance at a rapid pace. In light of this, ethical issues surrounding withholding or withdrawing life-prolonging medical treatment—for patients of any age—will present ongoing dilemmas for family physicians. However, the mandate to “serve as the patient’s or family’s advocate in all health-related matters” requires family physicians to participate in the resolution of these ethical dilemmas.

Additionally, as the physician who makes the initial diagnosis and provides the continuum of care, the family physician will need to cope with the broad range of social and health crises, such as the marked increase in teenage

pregnancy, infant mortality, and the spread of the human immunodeficiency virus. Because of their commitment to the patient and the family, family physicians need to keep current on the information and issues that contribute to the ethical and societal milieu in which they provide patient care, and, in many instances, they need to be prepared to serve as coordinators of ethical decision making.

Family physicians, because of their role in the lifestyles of their patients, also are involved in health and societal issues that affect the well-being of their patients. Ongoing concerns regarding occupational and environmental health as well as preventive health care measures have the potential to claim a larger role in the practices of family physicians. At present, for example, many family physicians are working with the AAFP and the AMA to bring about a smoke-free society.

As changing circumstances, such as the increased utilization of sophisticated health care technology, broaden the range of ethical issues, it will be important for graduate and postgraduate family practice medical education to keep pace. In addition to participating in the ethical decision-making process, family physicians have an opportunity in this dynamic health care environment to serve as their patients’ and families’ advocates. Family physicians, because of the level of their involvement, are in a position to represent the needs and interests of their profession and their patients in the ongoing debate over the delivery of health care.

Implications for the Future

In summary, the following factors are likely to influence the future socioeconomic environment of family practice:

- There could be a positive change in the status of family physicians within the medical profession, and the public will become more aware of the role of and need for family physicians.
- There may be a broadening of the sources of funding for residency training programs, particularly those that involve corporate funding.
- There is the potential for an increase in the demand for family physicians’ services, particularly as society places greater emphasis on continuity of care, preventive medicine, and health promotion.
- The demographics of the US population will change, including, most notably, a shift toward the health care needs of an older age group.
- The demand for family physicians may increase, particularly in managed-care settings, to utilize their broad range of health care services and their skills as case managers.
- There may be a shortage of family physicians, despite a predicted oversupply of physicians in general, particularly in managed-care systems and in rural areas that are underserved.
- Some aspects of family practice (eg, obstetrics) that

involve high professional liability insurance premiums may be further curtailed.

● Family practitioners will have an increased role in formulating and resolving ethical issues as they pertain to patients and their families.

The opportunities for family physicians clearly outweigh the constraints. Nonetheless, there are several avenues by which the medical profession can help ensure a favorable future practice environment:

1. The medical profession can continue to educate the public on the role and function of the family physician, the available forms of health care delivery, and health promotion and disease prevention.
2. The medical profession can promote and maintain high standards among physicians who practice family medicine by increasing the awareness of patients and physicians regarding ethical and bioethical decision making and by continuing to provide high-quality continuing medical education opportunities.
3. The medical profession can assume a leadership role by working with all the primary-care specialties to assure that quality health care is available in rural areas by supporting hospitals and physicians in those areas.
4. The medical profession can provide advocacy for the specialty of family practice by actively promoting the image and status of the family physician at all levels of the medical profession.
5. The medical profession can aggressively represent family practice at all levels of government and with all federal, state, and community agencies, be they public or private. Furthermore, the medical profession can work to assure that family physicians have access to affordable professional liability insurance and that they are treated fairly regarding reimbursement issues.
6. The medical profession must strive to ensure that family practice residency programs, in whatever setting, are of the highest quality and that graduates of these programs have been trained to deal with the complex ethical issues they will face throughout their professional careers.

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Combination Antiarrhythmic Therapy

JAMES E. TISDALE, PHARM.D.

COMBINATION therapy with antiarrhythmic agents is often used when therapy with a single agent is ineffective or only partially effective.¹ Additionally, therapy with a single antiarrhythmic agent may be poorly tolerated at doses required to prevent arrhythmias or to treat them effectively. Antiarrhythmic drug combinations may be better tolerated than single-agent regimens, because individual drug doses may be lower than those necessary when either agent is used alone.² Antiarrhythmic drug combinations are usually selected based on knowledge of the Vaughan Williams classification of antiarrhythmic agents³ (Table 1) and the electrophysiologic properties of the agents. The purpose of this paper is to review the advantages and potential toxicities of commonly used combinations of antiarrhythmic drugs.

Class IA and IB Combinations

Class I antiarrhythmic agents bind to sodium channels in myocardial cells and inhibit fast inward sodium current, thereby reducing the maximum rate of depolarization without affecting resting membrane potential.^{1,2} The affinity of individual antiarrhythmic agents for the sodium channels varies depending on whether the channels are in the resting (phase 4), open (activated, phase 0), or inactivated (repolarizing) phase. Class IA agents bind with greater affinity to open channels, for example, whereas class IB agents bind to open and inactivated channels with equal affinity.⁴ Therefore, blockade of frequency-dependent sodium channels with a combination of class IA and IB antiarrhythmic agents may be additive. Combinations of agents from these classes may have additive effects on conduction velocity and refractory period, and class IB agents may normalize prolonged QT intervals induced by class IA agents.⁵

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The most commonly used combination of class IA and IB antiarrhythmic agents is that of quinidine and mexiletine, and the efficacy of this combination has been evaluated in a number of studies (Table 2).⁵⁻¹⁵ These studies demonstrate that this combination may be effective in patients with ventricular arrhythmias in whom therapy with either agent alone has failed. Quinidine has also been used successfully in combination with tocainide for suppression of ventricular arrhythmias.^{16,17} Success rates with the combination of mexiletine and procainamide in patients with ventricular arrhythmias refractory to either agent alone have been similar to those determined using the quinidine-mexiletine combination.⁹⁻¹⁵ Mexiletine has also been used successfully with disopyramide.^{8,10,11,13-15,18} Experience with tocainide in combination with either procainamide or disopyramide is limited.¹⁹ Further study is required to determine the efficacy of tocainide in combination with these agents.

Based on data reported in a number of studies (Table 2) it appears that combination therapy with class IA and IB agents may be effective in approximately 20% of patients in whom single-agent therapy is unsuccessful,² and this combination may be associated with a lower incidence of extracardiac toxicity than use of single agents at higher doses.^{6,16,17,19}

Class IA and IC Combinations

Experience with combinations of class IA and IC agents is limited. Agents in both groups reduce ventricular conduction velocity, thereby prolonging the QRS interval. Additionally, class IA agents prolong repolarization, thereby prolonging the JT (QT-QRS) interval. Therefore, it might be anticipated that combinations of drugs from these two classes may have considerable proarrhythmic potential, and may cause additive undesirable effects on the electrocardiogram.² Klein et al²⁰ evaluated the efficacy of an investigational class IC agent, propafenone, in combination with quinidine or procainamide for patients with ventricular arrhythmias refractory to the class IA agent alone (Table 2). The addition of propafenone to quinidine or procainamide

resulted in statistically significant prolongation of PR, QRS, and QT intervals compared with class IA or propafenone monotherapy; two patients (6%) experienced a probable proarrhythmic effect when propafenone was added to their class IA regimen.

There is no available literature evaluating encainide or flecainide in combination with class IA antiarrhythmic agents.

Table 1
Modified Vaughan Williams Classification of Antiarrhythmic Agents³

Class I -	Sodium channel blocking agents
A.	Quinidine Procainamide Disopyramide
B.	Lidocaine Mexiletine Tocainide
C.	Encainide Flecainide
Class II -	Adrenergic beta-receptor blocking agents
Class III -	Inhibitors of repolarization Amiodarone Bretylium
Class IV -	Calcium channel blocking agents Verapamil Diltiazem

Class I and Class II Combinations

Adrenergic beta-receptor blocking agents (beta-blockers) antagonize the electrophysiologic effects of catecholamines.²¹ Catecholamines increase the rate of membrane depolarization, reversing the depression of phase 0 of the cardiac action potential that is induced by class I antiarrhythmic agents. Antagonism of this effect with beta-blockers may increase the potential for class IA agents to depress excitability, increase conduction time, and prolong the refractory period.²²

The most commonly reported combination of class I and II antiarrhythmic agents is that of quinidine and propranolol, which may be effective at controlling refractory supraventricular^{23,24} and ventricular²⁴⁻²⁶ arrhythmias. Results of some studies combining Class IA agents and beta-blockers²³⁻²⁷ are reported in Table 2. Combinations of beta-blockers with class IB agents have also been used successfully to treat refractory ventricular arrhythmias (Table 2).^{19,28} Further study is required to establish the efficacy of combinations of class IB and class II agents.

Experience with combinations of class IC and class II agents is limited. Evidence suggests that use of a class IC agent in combination with propranolol offers no advantage for control of ventricular arrhythmias compared with the beta-blocker alone (Table 2).²⁶⁻²⁹

Class I and Class III Combinations

Combinations of class I agents with amiodarone have been used in patients who have failed to respond to any other mode of therapy. Amiodarone has been used in combination with quinidine, procainamide, and disopyramide, both for prevention of ventricular arrhythmias

as^{30,33} and for maintenance of sinus rhythm after cardioversion of atrial fibrillation.^{32,34} Amiodarone has also been used in combination with mexiletine for control of ventricular arrhythmias.^{31,35-37} Based on data reported in these studies, the combination of amiodarone and a class IA or IB agent may prevent ventricular arrhythmias and atrial fibrillation in some patients refractory to conventional therapy. Experience with the combination of amiodarone and class IC agents is limited (Table 2).³⁸ Further study is required to evaluate this combination.

Combinations with Class IV Agents

Combination therapy with calcium channel blocking agents for arrhythmia control has not been extensively studied. The combination of verapamil and quinidine may be effective in preventing atrial fibrillation in patients refractory to quinidine alone.² The antiarrhythmic efficacy of verapamil³⁹ and diltiazem⁴⁰ in combination with propranolol has been evaluated. These combinations have been effective in treating some patients with paroxysmal supraventricular tachycardia (PSVT) (Table 2). Further study is necessary to establish the efficacy of combination therapy with calcium channel blocking agents.

Other Antiarrhythmic Combinations

Combinations of class IA antiarrhythmic agents may facilitate use of lower doses of the respective agents and reduce the incidence of adverse effects.^{41,42} Simultaneous use of two agents from this group may be successful in some patients, but the risk of proarrhythmic effects of this combination may outweigh potential benefits, particularly in view of the fact that many new antiarrhythmic agents have become available.²

There is no reported experience with combinations of class II and class III agents. Because amiodarone has electrophysiologic effects similar to those of beta-blocking agents,⁴³ this combination may have an additive effect on sinus node automaticity and atrioventricular conduction, and therefore may not be tolerated by some patients.¹

Drug Interactions

Combinations of class IA agents, as well as combinations of amiodarone and class IA agents, may result in prolongation of the QT interval and *torsades de pointes*.^{1,44} Drugs that have considerable negative inotropic effects, notably beta-blockers, calcium channel blockers, disopyramide, and flecainide should be used carefully in combination, particularly in patients with left ventricular dysfunction.

A number of pharmacokinetic interactions have been reported. Quinidine has been shown to elevate steady state serum procainamide concentrations approximately 70%.⁴⁵ Propranolol has been shown to increase serum flecainide concentrations by 25%.^{29,46} Amiodarone is known to increase serum quinidine and procainamide concentrations.^{47,48}

Table 2
Synopsis of Studies Evaluating Combinations of Antiarrhythmic Agents

<i>Reference #</i>	<i>Method of Evaluation</i>	<i>Antiarrhythmic Agents</i>	<i>n</i>	<i>Type of Arrhythmia</i>	<i>Antiarrhythmic Agent(s) Failed</i>	<i>Acute Efficacy # Pts. (%)</i>	<i>Chronic Efficacy # Pts. (%)</i>	<i>Mean Follow-up (Months)</i>
IA+IB								
5	EPS	Q+M	20	S-VT	Q,M	Q=2/20(10) M=1/20(5) Q+M=7/20(35)	Q+M=5/6(83)	14
6	AE	Q+M	21	NSVT, S-VT, VF	Q,M	Q=6/17(35) M=3/21(14) Q+M=16/17(94)	Q+M=10/14(71)	18
7	EPS	Q+M	89	S-VT,VF	Q	Q=30/89(34) Q+M=7/35 (20)	Q+M=6/7(86)	24
8	AE/ EPS	Q/ D+M	35	VPB's,S-VT,VF	M	NA	Q+M=6/8(75) D+M=6/6(100)	18
9	EPS	Q/ PA+M	23	NSVT,S-VT,VF	Q/PA/M	Q/PA=0/23(0) M=0/23(0) Q/PA+M=8/23(235)	—	—
10	AE/ EPS	Q/ PA/D/ P/ A+M	44	NSVT,S-VT,VF	M	M=7/23(30) Other = NA	5/7(71)	7
11	EPS	Q/ PA/ D+M	160	NSVT,S-VT,VF	Q,PA,M	Q=25/90(28) PA=24/70(34) Q+M=9/41(22) PA+M=4/15(27)	—	—
12	EPS	Q/ PA+M	76	NSVT,S-VT,VF	Q/ PA/M	Q/PA+M=21/76(28) Other = NA	—	—
13	EPS	Q/ PA/D+M	159	NSVT,S-VT,VF	M	M=29/128(23) IA+M=48/111(43)	M=20/30(67) IA+M=50/62(81)	19
14	EPS	Q/ PA/ D+M/T	166	NSVT,S-VT,VF	NA	IA=37/127(29) IB=13/127(10) IA+IB=20/127(16)	—	—
15	EPS	Q/ PA/D+M	105	S-VT,VF	NA	IA+M=2/15(13)	—	—
	AE	Q/ PA/D+M	105	VPB's,S-VT,VF		IA+M=7/29(24)		
16	AE	Q+T	14	VPB's,NSVT	Q,T	T=2/13(15) Q=3/13(23) T+Q=6/13(46)	—	—
17	AE	Q+T	20	VPB's,NSVT	Q,T	T=6/20(30) Q=9/20(45) Q+T=16/20(80)	—	—
18	EPS	D+M	12	NSVT,S-VT,VF	D,M	D=6/12(50) M=4/12(33) D+M=8/12(66)	D=3/3(100) D+M=5/7(71)	10
19	AE	PA/D+T	20	VPB's,NSVT,S-VT,VF	Q,PA,D,T,Pr	T=6/10(60) PA+T=0/2(0) D+T=2/2(100)	T=1/10(10) PA+T=0/2(0) D+T=1/2(50)	12
IA + IC								
20	AE	Q/ PA + Propaf	47	VPB's,NSVT	Q,PA	Q/PA=2/23(9) Q/PA+Propaf=16/23(70)	—	—
I + II								
24	AE	Q+P	77	AT A.fib/flutter NSVT,S-VT	Q,P	P=4/5(80) Q+P=8/13(62) P=8/34(24) Q+P=12/33(36) P=3/12(25) Q+P=8/11(73)	—	—
26	EPS	Q/ PA+P	74	NSVT,S-VT	L,Q,PA,E	PA/Q+P=5/29(17)	—	—
	EPS	P+E	74	NSVT,S-VT	E	E+P=0/6(0)		
27	AE	Q/ PA+N	18	VPB's,NSVT	Q/ PA	Q/PA=2/7(29) Q/PA+N=5/8(63)	—	—
29	AE	P+F	10	VPB's, couplets NSVT,S-VT	P,F	P=7/10(70) P+F=6/10(60) F=NA	—	—
I + III								
30	EPS	Q/ PA+A	37	NSVT,VT,VF	A	A=0/37(0) A+P=2/31(6)*	A=16/20(80) A+P=15/20(75)	14

Table 2 (Cont.)
Synopsis of Studies Evaluating Combinations of Antiarrhythmic Agents

Reference #	Method of Evaluation	Antiarrhythmic Agents	n	Type of Arrhythmia	Antiarrhythmic Agent(s) Failed	Acute Efficacy # Pts. (%)	Chronic Efficacy # Pts. (%)	Mean Follow-up (Months)
31	AE	Q/M+A	11	VEA	NA	Q/M+A=9/11(82)	—	11
34	AE	A+Class IA	10	A.fib	A,Class IA		A=8/10(80)	2-10
35	EPS	A+M/ Propaf.	32	NSVT,S-VT	A,Class IA	A=6/32(19) A+IA=14/26(54)	—	—
36	EPS	A+M	9	NSVT,S-VT, VF,VPB's	A,M	A=0/2(0) M=0/7(0) A+M=9/9(100)	A+M=4/9(44)	6
37	EPS	A+M	10	S-VT	A,M	A=0/10(0) M=0/10(0) A+M=10/10(100)	—	—
38	AE	A+F	24	VPB's,NSVT,S-VT	Multiple; not specified	A+F=11/24(46)	10/17(59)	up to 3 yrs
II + IV								
39	EPS	V+P	14	PSVT	V/P, Class I	V=7/13(54) P=4/13(31) V+P=11/13(85)	V=2/3(67) P=3/4(75) V+P=4/5(80)	13
40	EPS	Di+P	15	PSVT	none	Di+P=14/15(93) Placebo=4/15(27)	—	—

* While the arrhythmia only became non-inducible in two patients on this combination the mean ventricular tachycardia cycle length (VTCL) was significantly greater on the combination, and 16/31(52%) of patients on the combination were hemodynamically stable during VT, compared with 10/37(27%) on A alone.

IA = class IA agent

A = amiodarone

D = disopyramide

Di =diltiazem

E = encainide

F = flecainide

L = lidocaine

M = mexiletine

N = nadolol

P = propranolol

PA = procainamide

Propaf. = propafenone

Q = quinidine

T = tocainide

V = verapamil

AE = ambulatory electrocardiography

A.fib = atrial fibrillation

A.flut = atrial flutter

AT = atrial tachycardia

EPS = electrophysiology studies

NA = information not available

NSVT = nonsustained ventricular tachycardia

PSVT = paroxysmal supraventricular tachycardia

S-VT = sustained ventricular tachycardia

VEA = ventricular ectopic activity

VF = ventricular fibrillation

VPB's = ventricular premature beats

/ = or

Conclusion

Combination antiarrhythmic therapy may be beneficial for treatment of arrhythmias refractory to single agents, or in cases where required doses of single antiarrhythmic drugs cannot be tolerated. It should be emphasized that combinations of antiarrhythmic agents should be used only after treatment with adequate doses/serum concentrations of single agents has failed. Therapy should be individualized based on the patient's age, type and severity of arrhythmia, and concomitant disease status, particularly with reference to liver, kidney, and left ventricular function. Electrophysiologic testing is recommended to guide the selection of appropriate therapy for patients with malignant ventricular arrhythmias, and for those patients who may be at risk for sudden cardiac death.^{15,49-51}

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The Connecticut State Joint Practice Committee

MARY B. PRYBYLO, R.N. AND ROBERT D. STEIN, M.D.

THE Connecticut State Joint Practice Committee was established in 1972 by the Connecticut State Medical Society and the Connecticut Nurses' Association. It is a liaison Committee of physicians (who collectively comprise the Committee on Allied Health Services) and nurses, whose members are appointed by the parent organizations and who are drawn from private as well as hospital practice.

The Committee's objectives are similar to those of the National Joint Practice Commission which preceded it. These include:

1. The promotion of more effective communication among physicians and nurses.
2. The promotion of comprehensive planning and provision of optimal health services, regardless of delivery setting or practice structure, through interprofessional collaboration among physicians and nurses.
3. The identification of problems associated with adjustments of the basic roles of the two professions, as well as suggestions concerning feasible solutions.

Over the course of the past 17 years the committee has been involved in a variety of activities directed at furthering its objectives. It has assisted Connecticut's hospitals through workshops and invitational meetings in their efforts to establish their own hospital joint practice committees (presently at least 28 Connecticut hospitals have joint practice committees). It has examined issues such as the development of collaborative practice models, and has written position statements on collaborative education of medical and nursing students, principles of licensure for health care personnel, and development of criteria for establishing new categories of health care workers. It has discussed the development of policies concerning "Do Not Resuscitate" orders, "Living Wills," and "Death With Dignity." It has been monitoring the issue of cost-containment and its effects on quality of care, as well as the origins, magnitude, and implications of the nursing shortage.

Hospital joint practice committees have been involved in examining similar issues as well as the more tangible, clinical aspects of providing daily quality care. Specific issues addressed at the hospital level have included delineation of privileges for nurse practitioners and physician's assistants, development of "Do Not Resuscitate" criteria and policies, and establishment of policies for topics such as reintubation of extubated patients, or

responsibilities and restrictions relative to the administration of I.V. medications. Ethical issues have been discussed at this level as well, and some hospital joint practice committees have spawned ethics committees to lend further assistance and guidance to administrators, nurses, and physicians who have been confronted with related problems.

The State Joint Practice Committee is the only permanent, formal organization of its kind within the state, where representatives from the Connecticut State Medical Society and Connecticut Nurses' Association can work together on a regular basis. Such a forum for communication appears to be even more important now than it was 17 years ago, especially in the current atmosphere of intensified, and occasionally adversarial, competition among health care providers and institutions, the nursing shortage, and third-party efforts to usurp control of our patients' care.

There is concern that without adequate communication and cooperation between the two professions, the situation will only deteriorate further, leading to increased friction between physicians and nurses, more fragmented, lower quality care, and greater dissatisfaction among health care providers.

Current controversies include recent proposals for prescriptive authority for nurses, and for the development of registered care technologists. These, however, are but two of a growing number of issues that threaten to affect our practices and our attitudes towards one another, and that will most likely find their way to the legislature for refinement and approval.

Many of us believe that now, more than ever, there is a need for our two professions to stand together against those issues that threaten our very existence, rather than to allow a chasm to develop between us. It is for this reason that the dialogue must continue, and it is for this reason that logical, rational compromises must be reached. Our focus, after all, is delivery of the best available care to our patients. From this, all else follows. Without this we cease to be true professionals.

Our committee members therefore believe that it is imperative that we continue to meet on a regular basis in order to enhance the dialogue within our state. Issues must be addressed, a broad spectrum of opinion will be sought, and recommendations will be provided to our parent organizations.

Those who are able to participate are invited to do so, and may contact us through either the Connecticut Nurses' Association or the Connecticut State Medical Society. Your efforts and involvement will be appreciated by all of us, but most especially by our patients.

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Shoot Out at the RBRVS Corral

STEWART J. PETRIE, M.D.

JUST about everyone agrees that the most hotly debated, discussed, and contested issue in many years, has been the matter of the "RBRVS" (Resource-Based Relative Value Scale, also known as the Hsiao Harvard Relative Value Study.) Undoubtedly, there will be many versions, interpretations, and other articles regarding this matter in view of its great impact upon how medicine will be practiced. In this article, I will try to put in what I believe to be the most important elements of this discussion. While this will not be quite a "fast take" article, I will attempt to lean in that direction.

Many of you have read articles by a Harry Schwartz, Ph.D., a perceptive and excellent commentator on the medical scene. Unlike much of the media, he has been sympathetic toward American medicine and American doctors. We have a speaking acquaintanceship and I mentioned to him at the recent Dallas AMA meeting that "I could hardly wait to see what he was going to write in this matter." He answered that "he could hardly wait to see what he, himself, was going to write." Since I began this article he has, indeed, gone ahead with his incisive remarks published in *Private Practice*, January 1989. He observes that "perhaps the most influential speaker on the RVS issue is Nelson Richards, M.D., a Virginia neurologist, who represented his specialty in discussions with Dr. Hsiao conducted a week before the Dallas meeting. Dr. Richards reported that the Hsiao team has been radically affected by the firestorm of physician criticism that has spread in response to its initial findings. He said Hsiao has pledged that his group will do a better job of its remaining work. Based on Dr. Richards' comments, many delegates who were outraged by the initial Hsiao report decided to take a chance and vote for the resolution favoring an RVS, without in any way endorsing Hsiao's published recommendations."

"Cognitive" v "procedural" was envisioned as one of many problems. To understand the forces at play in this important contest, I shall begin by identifying the opposing parties and issues, and reminding ourselves of the forces that led to this study being undertaken. The US

government and HCFA are the chief contenders in this effort; if there are limited dollars to be spent on medical care, then some system for appropriate allocation has to be developed. Opposite this powerful force, one recognizes organized medicine as the champion of the patient's welfare and of the physician's continued ability to practice in a way best for patient care. Surely we understand that the system of diagnosis related groups (DRG)s would be much more unreasonable had the AMA not tried to work to make sense out of this unique way of determining Medicare payment.

In an editorial from the *Wall Street Journal* entitled "Medicare's Money Pit" the writer quoted Sen. Allen J. Ellender in 1965 as follows: "Let us not be so naive as to believe that the Medicare program will not be increased from year to year to the point that the government will have to impose more taxes on the little man or else take the necessary money out of the Treasury." To understand the dilemma that Congress must face, it is worthwhile to note not only the "over-promising" done initially in the Medicare program but also the budgetary constraints that now are impacting on us. The Money Pit editorial goes on to state that "within 15 years Medicare outlays will equal those for defense or Social Security. Only seven years after that, Medicare spending will equal that for Social Security and defense combined. The money pit becomes a black hole that threatens to suck in the entire budget. Medicare taxes the young to care for the old, but it offers the old no incentive to think about, much less restrain, the cost of their care. The elderly we know hardly want to burden their grandchildren, yet Medicare's socialist incentives are encouraging them to do just that."

Dr. Roper, of HCFA, seems much in favor of a capitation program (?decapitation). To make the issues even more difficult to define and manage is the fact of possible controversy between the so-called "cognitive" and the "procedural physicians." Before this study was begun, and certainly at regular intervals since that time, we have been admonished from above to keep our fences well mended and not allow divisiveness among physicians to become the "divide and conquer" method of government authorities. To muddy the waters still fur-

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ther, controversy also has sprung up between rural and urban areas. Geographic differentials in payment have been unfair in the past and attempts to remedy this have been considered at the same time with the matter of physician payment.

I must begin by stating that those who have not taken the time to learn what transpired could conclude that there was some sort of "sell-out" to RBRVS. Later I shall review the nature of this heated and lengthy reference committee debate, but for now, simply state that the report AA of the Board of Trustees is labeled "The National Study of Resource-Based Relative Value Scales for Physician Services: Evaluation of Final Report of Phase I and Implementation Issues." This is a long way from any *carte blanche* endorsement of the Hsiao study. In the nearly eight years that I have been a delegate to the AMA, I have seen many important issues debated at length and with great vigor. Excellent reports have come from the Board of Trustees and its councils regarding such matters as AIDS, nursing shortages, tort reform, and other legislative and scientific matters. This report, however, ranks high in importance; it runs to 43 pages and is an excellent study which was widely supported by the conclusion of our meeting. The need for unity and cohesiveness was strongly endorsed, even by those of our members who have the most to lose by it. Wide-based input into the AMA Board of Trustees study as well as the depth of perceptiveness of the shortcomings of the Hsiao report are clearly defined. As an indication of how far-reaching and important this report was held to be, I mention the following. At most reference committee meetings, there are usually fewer than six speakers lined up at the microphones; in this debate, the entire Sunday afternoon (and on into Monday as well), there were over 160 speakers and debaters on this topic. Wisely the AMA staff decided to ask this reference committee to start its work on Sunday afternoon, thus allowing the entire house to participate. No physician felt that he had to be elsewhere at some other reference committee and possibly miss important input and discussion on this document. In the end, there was wide consensus and commendation to the AMA board for their work on this report.

What are the shortcomings of the Hsiao report? How were the wounds healed in the matter of cognitive v procedure colleagues? What about geographic differences for payments? Where do we go from here? I shall quote directly from Report AA of the Board of Trustees from time to time, but will mostly list my own reactions to these proceedings.

At the 1988 Annual Meeting, the AMA House of Delegates adopted Board of Trustees Report 00. Report 00 described criteria for evaluation of the Harvard study of resource-based relative value scales (RBRVSs) for physician services and recommended that a full evaluation of the study be conducted before any implementation decisions

were made. Issues related to implementation of an RBRVS-based Medicare physician payment system were also reviewed in Report 00, and a policy recommendation supporting a transition period between the current Medicare physician payment system and any system involving payment schedules was adopted. Attention is also directed to the October 1988 issue of *JAMA*, since it was devoted exclusively to the Harvard study. The study began in December 1985 and a 2,000 page final report was submitted to HCFA in September 1988. Other alternatives to the RVRBS, even more unpalatable, would include such matters as DRGs, widespread capitation, Medicare PPOs, expenditure caps, and further constraints on Medicare's current customary-fee and unreasonable system. Mounting budgetary pressures have placed the Administration and Congress in a situation where all of the above have been considered. It is felt that these proposals undermine the independence of the medical profession and pose serious threats to the clinical decision making of physicians for their Medicare patients. In contrast, Association policy argues that an indemnity payment schedule based on an appropriate RVS could be the basis for a more acceptable Medicare physician payment system that would preserve fee-for-service medicine, while eliminating much of the complexity that has progressively plagued CPR.

This Board of Trustees report makes 19 recommendations related to this study; I shall list some of the more critical ones:

1. Recommendations in regard to relative value scale. That the AMA reaffirm its current policy in support of adoption of a fair and equitable Medicare indemnity payment schedule under which physicians would determine their own fees and Medicare would establish its payments for physician services using appropriate RVS factors and conversion factors.
2. That the AMA adopt the position that the current Harvard RBRVS study and data, *when sufficiently expanded, corrected, and refined*, would provide an acceptable basis for a Medicare indemnity payment system. (Much testimony was brought out that this study is actually incomplete in the case of many important specialties and thus *carte blanche* endorsement cannot be given.) Ongoing refinement and completion of the study is an important factor in its acceptance. This would include appropriate action to address concerns for individual specialties as well as a mechanism to ensure that additional concerns not be put aside but be brought to the attention of the appropriate parties with their proper validation as conducted by the AMA.
3. "Balance billing" is a nonnegotiable item since the AMA feels that this is important to ensure physician and patient rights to deal with each other in a traditional fashion. To the credit of the doctors present, it was also

heavily endorsed that the AMA support state and county medical society initiated voluntary assignment programs for low income, Medicare beneficiaries. (Connecticut physicians have been in the forefront with our courtesy card program.) In the meantime, recommendations further affirmed the AMA's opposition to the maximum allowable charge (MAAC) limits, as well as the importance of promoting and enhancing physician discussion of fees with patients as an explicit objective of Medicare indemnity payments.

It seemed important to me that there be a balanced billing policy along with the matter of transition to minimize disruption of patient-physician relationships during this period when corrections are made as needed. Eliminating geographic differentials are being addressed as well as consideration of access problems in specific geographic areas. The AMA should strongly oppose any attempt to use the implementation or subsequent use of any new Medicare payment system to freeze or cut Medicare expenditures for physician services in order to produce federal budget savings. There is an old saying: "fool me once, shame on you—fool me twice, shame on me." We have all seen it come to pass that in our zeal to help some new system get under way, we have accepted a slightly substandard fee only to find out that there was little possibility of ever changing the fee. The Board of Trustees addresses the updating of the fee schedule as follows: That whatever process is selected to update the RVS and conversion factor, only the AMA has the resources, experience, and umbrella structure necessary to represent the collective interests of medicine, and that it would seek to do so with appropriate mechanisms for full participation from all of organized medicine, especially taking advantage of the unique contributions of national medical specialty societies.

The last several pages of the report deal with an overview of the Harvard RBRVS study. In case you have wondered what the RB before RVS really amounts to, it concerns many matters other than physician charges (which have been the basis of previous relative value scales). The Harvard report argues that resource costs are more appropriate bases for RVS. Current AMA policy supports this view. To emphasize the ongoing nature of this Harvard study (rather than something which has been finalized and to be implemented as is), is the fact that Congress has mandated that initially 15 specialties be included. Harvard has been funded by HFCA to extend its study to these additional specialties in a second phase to begin this winter.

There are those who might wonder whether the persons in charge of validating this study were representative of medicine as a whole. For this reason, there were 14 technical consulting groups (TCGs) brought together, comprising representatives of 20 specialties, the American Board of Medical Specialties, six subspecialties of internal medicine, and oral-maxillofacial surgery. The weakest portion of the study is the lack of external

validity checks, ie, comparison of the survey results with other measures of resource costs. In this regard, the comments of the TCG physicians, who provided the strongest check on how well the survey results reflected clinical practice, do not receive sufficient attention in the study's final report. More detailed discussion of the TCG's reactions to the survey findings in the Harvard report might have provided more evidence for the validity of this measure of intraservice work.

In addition, it is clear that the study would have benefited from more timely provision of information to TCG physicians, as well as a greater responsiveness to some of their expressed concerns. AMA staff will work to ensure that use of the TCGs during the second phase of the study is improved to respond to these deficiencies.

The matter of balance billing has been given great scrutiny and analysis. The AMA has long opposed mandatory assignment and has supported physicians' right to establish their own fees. In addition, the AMA has had a number of concerns about the Medicare Participating Physicians Program and has sought repeal of it and the MAAC limits established in the current system. Although the Association was not successful in obtaining a court finding invalidating MAACs, the 14 October 1988 written opinion of the United States Court of Appeals, Fifth District, recognized the MAACs as being "ridiculously" complex, and as deterring top students from applying to medical school. The Association also urges physicians to consider their patients' ability to pay and to accept assignment or charge a reduced fee or no fee in instances of patient financial need. This was a "nonnegotiable" item because of the AMA's championing this position. The other equally important point is liberal acceptance of this payment as payment in full when there is any question of the patient's ability to pay. Attention is drawn to the editorial in the October 1988 issue of *JAMA* by J.S. Todd, M.D., which states:

No one should consider an RBRVS, which itself has no monetary meaning, as fulfilling the criteria necessary for a fixed fee schedule. The RBRVS, like any RVS, is based on averages An RBRVS-based system cannot recognize differences between physicians in patient mix, quality, or practice costs. Nor can it account for local market conditions that affect access to care.... A properly working RBRVS-based fee schedule will require the flexibility that comes with the ability to balance bill Rigid price regulations inevitably produce distortions that harm consumers and producers alike.

The final report of the Harvard RBRVS study indicated that if the RBRVS is to be used as a basis for a fee schedule, geographic variation in costs among physicians should be reflected in the conversion factor.

If you have waded through this article, thus far, and wish to take heart in some important outcomes of this

matter, address your attention to some conclusions and recommendations:

Continuing high rates of growth in Medicare expenditures for physicians services, and mounting pressure to reduce the federal budget, have made Medicare physician payment reform a focal point on Congress' agenda. Congressional and Administration attention to physician payment has to date produced fee freezes, MAACs, inherent reasonableness cuts, and proposals for widespread capitation, DRGs, Medicare PPOs, and expenditure caps. With the implementation of MAACs and inherent reasonableness cuts, the CPR system became moribund. The alternatives to CPR offered to date pose serious threats to the ability of physicians to continue providing high quality, accessible health care for their Medicare patients.

Medicine must have its own Medicare payment proposal. An RBRVS-based indemnity payment system has been viewed as a credible alternative and has already served the profession well in restraining some of the enthusiasm for more disruptive proposals. That the AMA adopted the position that the current Harvard RBRVS study and data, *when sufficiently expanded, corrected, and refined*, would provide an acceptable basis for a Medicare indemnity payment system."

The concept of balance billing seems only fair to the AMA and its member physicians, but will possibly be unpopular with Congress in their zeal to remain popular with their constituencies. We must offset our desire for balance billing by being extremely responsive to the medical needs of patients in low income brackets. Keep in mind that we have not accepted the Hsiao study as such but have accepted the AMA report the highlights of which are listed above. The fact is that there will be a gradual transition to such a program, that balance billing is an important part of it, that regular updating is to occur with it, and, most importantly, that it will not be a basis for payment until some of these wrinkles have been worked out. Lord Cardigan may have said to his light brigade "OK folks, let's take a little stroll down the valley to Balaklava." If we think of the government as Lord

Cardigan, then I believe the perceptiveness of the physicians studying this program will keep us from being deluded as to just what is happening.

Summary

1. If one understands and believes what has been noted above, then the conclusion is that some new system must be devised for payment of medical services.
2. While the Board of Trustees report in evaluation and recommendations of the RBRVS study was ultimately acceptable to the delegates, the Hsiao study was not. (It is incomplete and flawed in many ways and is to be reviewed further and ruled upon.)
3. The problems of rural v urban differential will be addressed.
4. A gradual phasing in of this entire program to avoid disruptions is mandatory.
5. The acceptance of a "balance billing concept" will be necessary and only fair to allow full access to medical care. There seems to be some "inherent reasonableness" to the fact that the well-to-do senior citizen would expect to be balance billed, and on the other hand, the indigent elderly person would receive excellent medical care, as proposed by our present "courtesy card program."
6. Ongoing surveillance by medical authorities will be needed to avoid the subversion that so often happens to well-intentioned programs.

Dr. Russell Roth (past president of the AMA) has helped lighten the atmosphere among many of our stormy debates over the years. He has done this by well designed and appropriate limerics. The one that he concocted for this particular problem goes as follows:

"It is true that our health depends,
On our congressional friends,
To grant this convention, this brief intervention,
Remember Jesus saves and Congress spends."

It can thus be seen from all of the above, that this "shoot out" wound up not being a deadly and divisive affair. A note of harmony allowed all of the factions to "spike their guns." Great credit for this belongs to not only the excellent report AA of our Board of Trustees but also to the long range perceptiveness of our membership who realized the necessity for this approach.

View from the Hill

JAMES E. BRYAN

TWO months ago, this column offered a general introduction to the most recent of a series of highly significant reports issued by the Institute of Medicine (IOM) on various issues affecting medical practice and the health of the American people. Titled "The Future of Public Health," this report deserves further attention.

The IOM's Committee for the Study of Public Health found, somewhat ominously, that public health vigilance has typically and generally slackened. It suggested that the central need is for "public concern and concerted action." However, despite avid public interest and deep concern about the AIDS problem and the mounting social crisis of drug dependency, the IOM study revealed a lingering public reluctance to accept the reality that health, in all its manifestations, is both an individual and a social responsibility. Of course, to participate in health-promoting activities, the public must be informed of the needs as well as the opportunities to support the protective services provided by the community.

The committee found wide variances among and within the states in the standards of performance and the degree of popular support for public health agencies and their programs. Many localities have no health department at all. Some states do not include environmental problems, prenatal care or mental health services in their public health agendas. Some combine health and social services without much depth in either area.

One recalls the agitation, two decades ago, for a National Department of Health, separate from welfare, education or human services. The designation of Otis Bowen, M.D., a family physician, as the first physician secretary of the Department of Health and Human Services has seemingly demonstrated that human services and health services are really interdependent—a concept that should help restore the public health mission to appropriate status in our popular value system.

Besides a growing failure of interaction between the clinical profession and public health professionals, the latter suffer a sort of vocational insecurity more typical of the political than the professional life. The committee reports that the average tenure in office for a state health officer is now two years. There is also a "growing perception of health as big business," which is surely a mistaken

perception as applied to professional public health administration and practice. This "has led to attempts to take public health out of the hands of the doctors" by subordinating the health officer to the nonmedical administrator.

The public health officers who would cultivate public knowledge and support for their efforts are hindered by the circumstance that crises, not successes, are the stuff of news in public health endeavors. Beyond that, the committee found that public health officers often ignore or discount the political realities of democracy or its relevance to their work.

Public support for research in public health areas and availability of technical expertise in the field suffer from the dearth of popular interest. Furthermore, low salaries, an inferior public image and declining professional prestige seriously hamper recruitment of competent leaders in the field.

The committee identifies the "core functions" of public health agencies as (1) assessment of health status, needs and problems; (2) leadership or assistance in developing policy, and (3) assurance that services and protections are financed, in place and available. The basic functions and responsibilities of the federal health authorities are summarized as research, information exchange, setting national objectives, providing technical help, subsidizing necessary services in the states, and assuring action and service to meet national health problems. The committee reminds us, however, that our government spends more at all levels on personal health and medical services than on population-based health functions, thereby tending to minimize the preventive function of medicine.

In a not uncommon sense, public health practice in the United States is a victim of its own successes. The health problems that public health practice was challenged to attack—safe water, protection against epidemic diseases, infant mortality and the like—have yielded as problems, but they persist to the extent they do because of a lack of vigilance or a failure to apply the meager funds needed to carry on.

An active, well-supported public health service is as essential to the welfare of our society as a competent, conscientious physician is crucial to an individual patient. We should add a public health effort to our roster of critical public interest deficits.

JAMES E. BRYAN, Washington Correspondent, *American Family Physician*.

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Family Practice

The report, "The Future of Family Practice," in this issue of *Connecticut Medicine* identifies some interesting facts regarding the specialty of family practice. Family physicians have the largest number of patient visits of any specialty, and family practice is the specialty in greatest demand in today's medical marketplace. Yet family practice has not gained status in the academic community. Family practice has certainly gained strength in medical schools since its inception as a specialty in 1969; however, as stated in the report, its status is still lacking. In the eye of the general public, though, the status and the need for family physicians has grown. This is evidenced by the demand for family physicians and the number of patient visits to family physicians. Why is the academic community unwilling to recognize and support training to satisfy this area of need in medicine today? The report gives a number of reasons for this lack of status: competition with other primary care specialties, lack of the traditional depth of other specialties, lack of a research and publication base, and lack of role models for medical students.

Competition does exist between family practice and other primary care specialties. The other specialties continue to produce physicians in their specialties, and by and large these specialists remain busy. Also, competition should be beneficial, with each specialty working to provide better medical care for our patient populations, rather than bickering with each other. Therefore, I do not see competition as a legitimate reason for lack of status.

The breadth of family practice does cause concern among those specialists who have trained in depth. When this is a true concern, it may be justified; when it represents elitism, it is clearly not justified. The academic community needs to examine its basis for not granting status to family practice to determine whether it is elitism or a true concern over the breadth of training for family practice.

To date, family practice has not emphasized research and publication as much as the other specialties, although research is being done and there are excellent journals of family practice. The slow development of research has been the appropriate approach since, as a new specialty, family practice needed to develop a strong clinical base. Without such a base, research could not be performed and accomplish meaningful results. Family practice is a clinical specialty and, therefore, its research should be primarily in clinical fields. As family practice departments become stronger and family practice residencies more stable, research has begun to develop in the specialty. As noted, funding for research in family practice is

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a significant problem and the specialty will need to develop methods for funding meaningful research.

Although research is important, I believe the academic community must reevaluate clinical teaching and recognize it as being just as important. For instance, many of us involved in residency training programs identify two major deficiencies in American trained medical students entering our residency programs. One deficiency is the inability of entering residents to take an adequate history and perform a skillful physical examination and interpret their findings. The other is the lack of clinical problem solving abilities in an ambulatory care setting. These are basic to good medical practice and are being neglected in medical school clinical education. Clinical medicine should be valued by medical schools on a par with research if we are to continue to maintain an excellent medical care system in this country. Family practice is a clinical specialty which could, and should, be a leader in teaching and demonstrating good clinical medicine.

The need for role models does exist in the academic setting and will continue to exist until the academic community recognizes the role and value of the family physician. Role models are available in the community, and these physicians must be utilized by the medical schools until they develop strong departments.

Family practice must continue to address the problems of funding for residency programs. Federal and state funds have been available to date and may be available in the future. However, other sources of funding are being investigated by family practice.

Reimbursement has been a problem for family practice. Nevertheless, the majority of physicians in practice are satisfied with their total practice situation. The RBRVS represents a hope for improving the financial outlook for family physicians.

Family practice as a specialty has grown in numbers and status since its inception. The specialty is committed to providing excellent medical care to the communities of this country, both rural and urban. The proliferation of specialties in depth has led to a lack of available and appropriate care for large segments of our population. Family practice has recognized this lack of care and has endeavored to develop specialty training in breadth to fill the gap. The medical community has a responsibility to all segments of our population, not only those in tertiary care hospitals. We must recognize this responsibility and work together to train physicians to provide this care. Cooperation is needed at all levels of care, from training medical students to relationships between physicians in practice. By developing a cooperative attitude, we can not only have the best technology and tertiary care medicine, but also supply excellent medical care to all segments of our population.

Dewees H. Brown, M.D.

Middletown, CT

Informed Consent and Common Sense

In my role as an attorney for hospitals, other health care facilities and associations, and physicians, I have advised clients and written extensively on the doctrine of informed consent for a number of years. Recently, I have thought a great deal about the philosophical aspects of the doctrine and have concluded that it is in need of surgery. As it has developed and been formed by the courts, it just cannot be squared with reality in certain important areas. In addition, I believe that the doctrine seems to be abused in that it sometimes appears to be used as a device to provide recovery to a patient who has experienced a bad result when negligence cannot be established, even though there has been an attempt to inform the patient which, upon analysis after the fact, was not perfect.

The courts have developed the doctrine of informed consent with the implicit assumption that it is possible fully to inform a patient about the advisability and the risks and benefits of the procedure in question. This assumption often is at variance with the facts.

Not infrequently, for example, there is clear and sometimes heated disagreement among the "experts" as to whether or not procedures should be performed.

In addition, the medical literature often is conflicting if not confusing in regard to the frequency of a risk occurring. In the use of low osmolality contrast media, for example, the literature offers research studies showing the risk of death ranging from one chance in 10,000 or so to one chance in many hundreds of thousands. Some of the studies showing extremely low risks have been seriously questioned by the leading expert on the use of such media as indicated in our recent article on the subject (*Conn Med* 1988;52:87-91).

Does it really make sense to require the physician to inform the patient, for example, that three articles support performing the procedure while two do not; or that the magnitude of the risk depends upon which study you want to accept? Obviously, even a Connecticut physician, who is required to meet a hypothetical national standard of care, cannot be expected to analyze the research methods and statistical controls used in each study and then present his own analysis to the patient, nor can he be expected to hire his own experts to attempt to understand and resolve the conflicts contained in the

literature.

In addition, does it make any sense to require that courses of treatment that clearly are inadvisable from a prevailing point of view nevertheless have to be disclosed and explained?

Or, does it make sense to provide a large recovery when there has been no negligence and there was an attempt to inform the patient and obtain consent, even though it was not perfect when viewed with hindsight?

In my view, we should consider adopting by statute a consent requirement which provides that the physician is not required:

- (1) to resolve or sketch out in any detail all disagreements as to the advisability of the procedure or disagreements as to the magnitude of the risks involved;
- (2) to inform the patient about alternatives which generally are not considered advisable; nor
- (3) to inform the patient about risks which are not generally considered to be significant or risks generally thought to occur rarely.

Finally, and most importantly, if there has not been any negligence there only should be recovery under the doctrine of informed consent if there has been a complete or serious failure to inform the patient about major known risks. The doctrine should not be a device which can be used when negligence cannot be established and there was a reasonable—albeit imperfect—effort to inform the patient. Recovery under a claim of failure to obtain informed consent should only be permitted if:

- (1) it is established by expert testimony that the failure to inform was very serious in light of the failure to disclose major risks which generally are known and routinely are disclosed; and
- (2) the trier of fact (judge or jury) also concludes that if there had been full consent a reasonable patient might have decided to forego the procedure.
- (3) In addition, if it is determined under (1) and (2) above that there should be a recovery by the patient, in calculating any damages the court must consider, in mitigation of such damages, the patient's probable life expectancy, or probable condition without having had the procedure, as developed by expert testimony.

J. Michael Eisner, Ph.D., J.D.

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The President's Page

Reform From Within



It was most heartening to me in early January to read a newspaper account of the Connecticut Supreme Court ruling that lawyers may no longer tell juries how much money their clients should receive in damages for pain and suffering. The amount of such proposed payments has always been based on intangible and even capricious estimates resulting in inequitable decisions, in my view, with greatly variable awards for the same or similar outcomes of accidents, malpractice or other liability situations.

I believe this ruling partially corrects the problem of noneconomic damages. The Supreme Court Justices have apparently changed their minds about the fairness of allowing plaintiffs' attorneys to attempt to influence juries directly on the size of awards. It is gratifying to see that our legal system still has the ability to adjust from within, thus avoiding the sensationalism and adversarial reaction when such reforms are attempted by legislative mandate.

This new ruling was arrived at after the review of two cases, one a malpractice case with an exorbitant award, and the second an accident case where a jury awarded the \$30,000 that the plaintiff's attorney recommended as compensation for 46 days out of work and continued complaints of neck and arm pain. As the Supreme Court stated, "when a jury arrives at an award of damages, if any, they do so as the neutral and impartial triers of fact. Suggestions by a plaintiff's counsel, on the other hand, are statements made in the course of the zealous representation of a client's cause, and therefore are completely self-serving."

More specifically, in one of the cases Judge David M. Shea stated that "the practice of mentioning the sum to be awarded to the plaintiff for pain and suffering constitutes an unwarranted intrusion into the domain of jurors," and that stating the amount claimed "encourages exorbitant demands by counsel."

As I stated previously, this is a laudable but only a partial correction of the problem. It would not seem to be such a large step from there to a more rational system of awarding noneconomic damages which are comparable between cases of similar nature, and thus more predictable. By definition, non-economic damages are difficult for jurors and others to assess fairly in economic terms.

Several alternatives are already available to accomplish this change, and I would hope that the courts would consider such further reform. As physicians whose significant medical liability insurance premiums pay for the bulk of the medical malpractice portion of the awards system, I believe we have a significant interest in this reform, and hope that this concept can be brought to fruition.

If it doesn't happen from within, then I believe it would be worthwhile to promote it legislatively, not only for us, but for other individual and corporate defendants, such as other professionals, hospitals, stores, schools, and municipalities.

Norman A. Zlotsky, M.D.
President

AFTERNOTE: "ConnMap"

With the Council's approval, we are urging all physicians to continue honoring the old CSMS Medical Courtesy Cards beyond the deadline of 12-31-88, and to advise their senior patients who have not yet applied for a replacement "ConnMAP" card to contact the Department of Aging immediately at 1-800-634-8852. It has come to our attention that many seniors have not yet had their CSMS cards replaced by the State of Connecticut Medical Assignment Program (ConnMAP).

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Reflections on Medicine

Too Much Science?

ROBERT U. MASSEY, M.D.

You may recall that in the opening paragraph of his essay, "The Care of the Patient," Francis Peabody wrote.

The most common criticism made at present by older practitioners is that young graduates have been taught a great deal about the mechanism of disease, but very little about the practice of medicine—or, to put it more bluntly, they are too "scientific" and do not know how to take care of patients.¹

Last year, 60 years later, Samuel Thier spoke of the criticism aimed at house officers and medical students that they were inhumane and excessively scientific, and then added, "When you stop hearing that new graduates are too scientific, it means the field is not advancing and training them better than the old..."²

Both Peabody and Thier were trying to say that medicine should not be either all science or all humanism (although Peabody did not use that term), nor, I believe, were they implying that it was a little of each. In 1927 scientific medicine was still a novelty for many doctors over 45; there were practitioners in their 50s and 60s whose medical school years had been at the threshold of modern scientific medicine and who might have had little instruction in bacteriology or biochemistry. They would have resented those coming out of Harvard, Yale, Hopkins, or Michigan, and would not have understood much that they were talking about. They would have feared competition from the newcomers who knew so much and whose knowledge seemed so marvelous to their patients. It was a time when faith in scientific progress was running high, and the modern doctor in the eyes of many was the epitome of the scientific man. Peabody pointed to the "amazing progress of science in its relation to medicine during the last thirty years," but went on to give the "practitioner of the older generation" his due: there was much in his art to teach the new crowd.

Thier, I believe, referred to criticism coming from without, the questioning of biomedical science and technology that has stubbornly persisted, especially among

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those who came of age in the '60s, as well as among some social scientists and public health people whose concern is more with denominators than with numerators, with populations rather than individuals.

Medical schools have tried to resolve this problem by bringing in the humanities, and by urging undergraduates not to neglect history, literature, languages, and philosophy during their four years of college. All of this is good for education and adds to the quality of the physician's life, but there are no data showing that humanists are more humane than scientists or better practitioners of the art.

Peabody and Thier came to similar conclusions: the merging of science and art occurs in the clinic or at the bedside or not at all. "The treatment of a disease may be entirely impersonal; the care of a patient must be completely personal," wrote Peabody, and he might have added that the care of patients is no less important because there is "nothing the matter with them." Indeed it was these patients with their headaches and backaches, belly pains and insomnia, depression and anxieties that always baffled young physicians from academic teaching hospitals, whether in 1989 or 1927.

Dismiss them with a "There's really nothing the matter with you," or knock them low with diazepam, and they will soon dismiss the whole profession and seek help from some "alternative" practitioner. When science fails, they, and even we, may turn to magic. But the skillful physician has something more than science, never to use in its place, yet not magic either, and that is his understanding of what Osler called "this deliciously credulous old human nature in which we work." These things are taught and learned at the bedside and in the clinics, and for those with eyes to see them, in novels, plays, and poetry, but rarely in behavioral science courses. They are taught mostly by example and learned only by experience.

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Winter Reading: The Past and Future of Health Law

JOSEPH M. HEALEY, J.D.

PHYSICIANS interested in understanding law and its increasing role in regulating the health care process are confronted with an impressive, if not imposing, array of books, journals, and articles. For most of these readers, however, it is not always clear where to begin or how to keep up to date. Complicating this search for understanding is not only the difficulty of keeping pace with any rapidly changing field, but also the difficulty of acquiring the breadth necessary to be comfortable with the wide range of topics and perspectives embraced under the heading of health law. Legal and ethical issues within the doctor-patient relationship, such as those raised by the McConnell case, are one aspect of health law involving the rights, duties, and goals of the various parties. Larger policy questions such as how best to deal with cost and quality issues are a second aspect involving legal regulation of the professional and commercial dimensions of the health care process. Each represents a different perspective and each requires a different approach. Two recent health law volumes, each by a different health law scholar and each emphasizing a different aspect of health law, provide a good place to start or to continue one's self-education in health law. One book emphasizes the major cases and issues dealing with patient rights during the past fifteen years. The other emphasizes the regulatory aspects of health care as a business. Together, the two volumes provide a useful starting point for the interested reader. This month's column will focus on the first of these books.

George J. Annas is the Utley Professor of Health Law at Boston University School of Medicine and Chief of the Health Law Section at Boston University School of Public Health. In *Judging Medicine*,¹ he has collected 61 of his articles written during the past 15 years. Most of the articles originally appeared in the leading journal for those interested in health law and medical ethics, *The*

Hastings Center Report. The articles have been organized by theme into nine sections: patient rights; conception; pregnancy and birth; reproductive liberty; medical practice; the mentally retarded and mentally ill patient; death, dying, and refusing medical treatment; government regulation; and transplants and implants. The individual articles are usually four to six-page discussions of what are now recognized as the leading cases and controversies during the past 15 years including: abortion, surrogate parenting, maternal-fetal conflict, decisions in the neonatal intensive care unit, malpractice, and decisions about withholding and withdrawing support at the end of life. The articles reflect the development of health law during this period of great activity when cases involving ordinary people, such as Karen Quinlan, Baby Doe, and Elizabeth Bouvia, attracted worldwide attention. This has been a period during which many claims by patients have been recognized as legally enforceable rights by courts and legislatures. Emphasizing his longstanding interest in analyzing the rights and duties of patients and health practitioners, Professor Annas provides a look back at how health law principles have developed in and through these cases and a look forward at the unfinished agenda which remains. Professor Annas is a perceptive analyst and commentator. He provides a strong and articulate voice for the patient rights perspective and he challenges health professionals to reexamine the goals and the content of their relationships with their patients in light of the evolving recognition of the legal rights of patients. His volume is a stimulating introduction to this aspect of health law.

Next month's column will discuss Clark Havighurst's new volume, *Health Care Law and Policy: Readings, Notes, and Questions*.²

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BOOK REVIEW

Life, Death, and Public Policy

By Robert H. Blank. 177 pp. DeKalb, Northern Illinois University Press. 1988. \$8.50 (paper); \$22.50 (cloth).

In presenting an "overview of the hard life-and-death decisions" that we as a society face as the result of recent rapid advances in biomedical technology, Blank concisely describes both the technological developments themselves and the evolving policy concerns that they engender. He touches on such wide-ranging subjects as eugenics, sex selection, genetic counseling and screening, abortion, sterilization, prenatal diagnosis, artificial insemination, in vitro fertilization, fetal research, psychosurgery, electrical brain stimulation, drug therapy, and organ transplants. In covering so many complex topics in so little space, Blank is admittedly not attempting to provide an "in-depth analysis of any single biomedical technology." He does, however, accomplish his stated goal of focusing on "the broader social-policy dimensions raised by [the] biomedical revolution in which even the basic definitions of life and death are challenged."

For Blank "all biomedical technologies focus fundamentally on the question of the extent to which we ought to intervene directly in the human condition." He has divided this book into six chapters with most technologies grouped according to their impact at a particular stage along the life cycle. Chapter one sets up the policy context and describes the "broad assortment of biomedical technologies" that have recently surfaced. Blank warns that "only major alterations in the U.S. health care system can avert a crisis of immense proportions in the coming decades." He asserts that in the United States the "distribution of medical resources is heavily skewed toward a very small proportion of the population." Two factors contributing to this are the emphasis that Americans have traditionally placed on the concept of individual rights and our societal "obsession with [the] prolongation of life." Blank sees increased governmental involvement in setting policy as unavoidable. His insights, however, would be more useful if the reader were provided with information as to his own professional background and perspective. Nowhere, at least in the paperback edition, is it revealed that the author is a professor of political science at Northern Illinois University and, because of the breadth of technical, legal, social, and ethical information conveyed, this omission as to his own frame of reference, is somewhat distracting.

Chapters two and three are perhaps the book's richest. Chapter two deals with "Human Genetic and Reproductive Intervention" and chapter three with "Prenatal Intervention." Here Blank demonstrates the effect of biomedical innovations on fundamental societal values. He points out, for example, that although some advan-

ces "promise to alleviate the individual and social costs of genetic disease and give us more control over the destiny of future generations... widespread use of these technologies expands considerably our ability to label and categorize individuals according to precise genetic factors—thus effectively minimizing the human aspects of humanhood." Although he can only cover each topic superficially, he raises important questions and offers diverse insights from many well-respected sources. Blank examines the policy implications relating to reproductive technologies in a context that includes questions about reproductive rights as well as potential reproductive responsibilities.

Chapter four, entitled "Biomedical Issues Within the Life Cycle," explores questions surrounding the neonatal ICU, organ transplantation, behavior modification or control via medical intervention with drug therapy and psychosurgery, and human experimentation. In addition to highlighting policy issues, this chapter is valuable for its compilation of interesting statistics concerning neonatal illness and mortality rates and for data pertaining to transplantation procedures in the United States.

In chapter five, "Death Related Issues in Biomedicine," the focus is primarily on classification and distinctions pertaining to euthanasia. Some recent court cases are outlined and a somewhat cursory reference is made to Alzheimer's Disease as an illness that will, according to Blank, have increasing policy ramifications.

The final chapter, "Policy Decisions in Biomedicine: Making Hard Choices," examines questions of allocation. Blank asserts the "even more critical than the general public's support for resource allocation is the cooperation of the health-care profession." He goes on to say that "physicians are particularly key decision makers on the demand side of medicine, since they serve as gatekeepers for access to treatment regimens, technologies, and drugs." Although he presents arguments for and against assigning the physician to this role, Blank writes that "despite its hesitency, the medical profession increasingly will find itself in the difficult position of responding to government initiatives and, eventually, to public pressures to make difficult allocation and rationing decisions."

Life, Death, and Public Policy provides a well-researched overview in which Blank has compiled many different views and perspectives. This volume, as stated in the preface, serves to introduce a new NIU Press series entitled, *Studies in Biomedical Policy*. In addition, the bibliography provides a wealth of information for those who would like to continue with more extensive study into specific subject areas.

Nancy R. Williams, J.D., LL.M.
Farmington, CT

Letter to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

LIFE AFTER...

To the Editor: Ms Kendrick's article in the December issue of the *Journal* must surely affect anyone who reads it. Its recital of repeated surgery, repeated bewilderment is deeply touching. Is her experience altogether exceptional and uncommon? Alas, no.

In my work for the state I talk with patients, or ex-patients, and review their records. All the patients have undergone treatment, often surgical. In one language or another they comment, freely for the most part, on the treatment received. Don't look for compliments; this is the group for whom medical efforts have failed. Yet anger, as described by Ms Kendrick, seems absent. If it's there, concealed, balance returns with the striking expressions of faith some of the patients have in their doctors. The stories are rarely dull and occasionally reach the poignancy of Ms Kendrick's recital. One often wishes the caregiver were there to hear.

Ms Kendrick would like "to open communication between the medical profession and patient." Fine. For physicians the lines of communication are open and abundant. How is the patient to communicate? Do we know his, or her, views with any certainty?

Let's invite the volunteer corps of our various hospitals to a new challenge. Each volunteer group is likely to contain one or two dedicated individuals who'll be intrigued. In some sort of random selection, hospitalized patients will be interviewed by the volunteers to explain the study and establish individual liaison. Consent, obviously, will be required of both patient and attending physician. After the patient's discharge the volunteer keeps in touch by telephone, in time becoming familiar with the patient's considered view of his course. To this point the study may resemble the follow-up questionnaires hospitals sometimes send to discharged patients. But what's sought here is the patient's unframed, mature evaluation of treatment received and its effect. When the picture becomes focused it's put into story form by the volunteer, all names omitted and using the patient's own words as much as possible. Then the story is submitted to the *Journal* for publication.

Will all this effort be worthwhile? Yes, according to Ms Kendrick. She states, meeting no objection from this quarter, that "Life experience speaks clearly, it is our greatest teacher."

Russell V. Fuldner, M.D.

Hamden, CT

Edward Luchansky, M.D., a Fairfield obstetrician/gynecologist recently was re-elected as vice-president of the Civil Aviation Medical Association. This organization, composed of aviation medical examiners and airline medical directors from all over the world, is concerned with the health and well-being of all civilian pilots and with the promotion of public aviation safety. Dr. Luchansky is a Federal Aviation Administration Senior Aviation Medical Examiner and serves as a flight surgeon in the Civil Air Patrol.

The Hartford County Medical Association has scheduled **Medical Expo '89** for 5 and 6 April at the Hartford Civic Center. This will be the fourth year that Hartford County physicians have sponsored the region's premier medical and health exhibition in efforts to make available the latest information on key issues facing the health care community.

The symposia program this year is entitled, "On the Leading Edge," and will focus on two areas of research that have been the subjects of almost daily headlines in the news: **heart disease** and **cancer**. Expo '89 will highlight recent developments with a program that will explore: **Innovative Cancer Treatments via Biotherapy**; the debate on **Whether the Costs of New Technology in the Treatment of Cancer and Heart Disease Are Justified by the Benefits**; **New Drugs in the War Against Cancer & Heart Disease**; and the AMA nationwide **Campaign Against Cholesterol**.

Throughout the two days of Medical Expo '89, an estimated 250 exhibitors will show their products and services. The exhibition will also feature extensive nursing recruitment activities of hospitals and health care facilities from throughout New England.

A symposium entitled, **Safety of the Blood Supply**, will be held in Farmington, at the American Red Cross Connecticut Region on Wednesday, 12 April 1989 from noon to 5:00 p.m. This symposium, to be moderated by **Dr. Edward L. Snyder**, is designed to inform physicians and allied health care professionals about the safety of the blood supply and methods used to decrease the risk of disease transmission. The symposium is jointly sponsored by Yale University and the American Red Cross Connecticut Region. Fee: \$20.00.

Those interested should call the Office of Graduate and Continuing Education, Yale University School of Medicine, 333 Cedar Street, P.O. Box 3333, New Haven, 06511; or call (203) 785-4578.

The **25th Annual Cardiovascular Symposium** sponsored by the Section of Cardiology, Saint Francis Hospital and Medical Center, will be held at the Hunt Memorial, Hartford Medical Society, 230 Scarborough St., Hartford, on 3 and 4 May, 1989. The fee is \$80.00. Those interested should contact Robert M. Jeresaty, M.D., Director, Section of Cardiology, Saint Francis Hospital and Medical Center, 114 Woodland St., Hartford 06105.

IN MEMORIAM

CARTER, MAX G., Harvard, 1941. Dr. Carter was a thoracic and cardiovascular surgeon in the New Haven area since 1949. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died 16 January 1989 at the age of 73.

CUSHMAN, LAURENCE A., Harvard, 1924. Dr. Cushman was a general practitioner in the Hartford County area since 1928. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died 28 December 1988 at the age of 91.

FINK, MARTIN E., State University of New York, 1957. Dr. Fink was an internist in the New Haven County area since 1960. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died 8 November 1988 at the age of 60.

LANSE, STEVEN B., SUNY at Buffalo, 1977. Dr. Lanse was an internist in the New Haven County area since 1982. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society and the American Medical Association; died 6 November 1988 at the age of 37.

MACGREGOR, JAMES, University of London, 1928. Dr. Macgregor was a general practitioner in the Fairfield County area since 1955. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died 11 November 1988 at the age of 84.

MCKEON, JAMES J., Hahnemann, 1939. Dr. McKeon was a general practitioner in the New Haven County area since 1940. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society; died 11 November 1988 at the age of 76.

OSTER, KURT A., University of Cologne, 1934. Dr. Oster was an internist in the Fairfield County area since 1943. He was a member of the Fairfield County Medical Society, the Connecticut State Medical Society and the American Medical Association; died 24 November 1988 at the age of 79.

PACE, SILVIO F., University of Rome, 1952. Dr. Pace was a general practitioner in the Hartford County area since 1958. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died 6 November 1988 at the age of 62.

REYNOLDS, ROBERT G., Harvard, 1926. Dr. Reynolds was an orthopedic surgeon in the Hartford County area since 1927. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died 22 December 1988 at the age of 90.

SCHECHTMAN, CHARLES T., University of Vermont, 1926. Dr. Schechtman was an ophthalmologist in the Hartford County area since 1930. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died 1 January 1989 at the age of 88.

SMITH, JAMES T., Long Island College of Medicine, 1941. Dr. Smith was a general surgeon in the Litchfield County area since 1947. He was a member of the Litchfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died 30 November 1988 at the age of 75.

SMITH, JOSEPH J., University of Maryland, 1930. Dr. Smith was an internist in the Fairfield County area since 1933. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died 21 November 1988 at the age of 84.

SONGCO, MARIANO F., University of the Philippines, 1954. Dr. Songco was a psychiatrist in the New London County area since 1958. He was a member of the New London County Medical Association and the Connecticut State Medical Society; died 6 January 1989 at the age of 60.

WEED, CLAYTON B., JR., New York Medical College, 1947. Dr. Weed was an internist in the Fairfield County area since 1948. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died 15 January 1989 at the age of 66.

ZSIGA, ELMO D., Marquette, 1938. Dr. Zsiga was a general practitioner in the Fairfield County area since 1938. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died 4 November 1988 at the age of 72.

From the Executive Director's Office

COUNCIL MEETING

Wednesday, January 11, 1989

Attendance

Present in addition to the Chairman Dr. Joseph C. Czarsty and Vice-Chairman Dr. Joseph S. Sadowski were Drs. Ahamed, Beck, Bobruff, Bonner, Chmielecki, Eslami, Freedman, Hollister, Kamens, Kaufmann, McDonnell, Orphanos, Robbins, Schwartz, Van Syckle, Welch, Wetstone, Zanker, Zeppieri and Zlotsky.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Sullivan, Mr. Staples, Mr. Tomat (FCMA), Mr. Coffee (HCMA), Mr. Freberg (NHCMA) and Mrs. Reed (President, Auxiliary).

Absent were: Drs. Catrini, Dardick, Fox, III, O'Brien, Petrie, Reyelt, Jr., Rose, Rubin, Sosa, Upham and Villa.

Dr. Joseph C. Czarsty, Vice-Chairman of the Council called the meeting to order, since Dr. Guy W. Van Syckle, whose term as Delegate to the AMA terminated on 12/31/88, thereby was no longer a member of the Council.

Councilor-At-Large

Dr. Czarsty called on Dr. James P. Orphanos, Councilor-at-Large and Alternate Delegate to the AMA, who submitted a resolution which outlined that he held a dual position on the Council and that Dr. Van Syckle's experience and wisdom should not be lost to the Council, he requested that the Council waive normal procedures, not to be interpreted as precedent setting, and accept his motion, "that it, in one unanimous vote, nominate, second and elect Dr. Van Syckle to the seat of Councilor-at-Large for the period effective immediately to the date of the 1989 Annual Meeting of this Society while simultaneously accepting his resignation vacating that seat in Dr. Van Syckle's favor." It was VOTED to unanimously approve the motion.

Election of Chairman and Vice-Chairman of the Council

It was VOTED to unanimously elect Joseph C. Czarsty, M.D., Oakville, Chairman and Joseph S. Sadowski, M.D., Hartford, Vice Chairman.

Presentation to Guy W. Van Syckle, M.D.

Norman A. Zlotsky, M.D., President, presented the following resolution to Dr. Van Syckle:

"Whereas: Guy W. Van Syckle, M.D., has served the Council with distinction as its chairman from 1981 until his retirement from the AMA delegation effective December 31, 1988; and

Whereas: Dr. Van Syckle has ably served the Connecticut State Medical Society as a delegate to the AMA, the chairman of its delegation and chairman, as well, of the New England delegation; therefore be it

RESOLVED: That the Council formerly acknowledges the substantial contributions which Guy W. Van Syckle, M.D., has made to all facets of medicine and wishes him well in his future endeavors."

Dr. Van Syckle addressed the Council briefly expressing his pleasure in working with members of the Council, presidents and staff during his term as Chairman of the Council. He reported that CSMS should be proud of its many achievements, especially the development of the Connecticut Medical Insurance Company (CMIC), CPRO and M.D. Health Plan, which have received national recognition.

Committee on Legislation

Dr. Czarsty submitted his resignation as chairman of the Committee on Legislation and it was VOTED to approve Dr. Zlotsky's nomination of Howard J. Whetstone, M.D., Hartford, as chairman.

Physicians Serving on State and Federal Agencies

Roger Beck, M.D., CSMS representative for the Department of Health Services Ad Hoc Committee on Prescriptive Authority for Nurses, reported that this is a very controversial subject and gave the following background information: The committee is made up of one physician, two pharmacists, about six nurses plus a representative from the state narcotics division and an attorney for the state who also happens to be a nurse. The issue of prescriptive authority for nurses was raised by an HMO who requested the narcotics division to grant that their nurse practitioners be allowed to prescribe. The request was submitted to the Attorney General who determined that this practice would be illegal. This determination was not welcomed by the Division of Community Services and Home Health Care of the State Department of Health Services. It appears that there are nurse practitioners prescribing now in numerous locations with and without the sanction of the state in various clinics, nursing homes, schools, colleges, etc. It has become apparent that the Department of Health Services will attempt to change the statutes to include nurse prescriptive authority, therefore, a statement of conditions concerning the broadening of the statute was developed by CSMS representatives and legislative counsel and given to the Department of Health Services and it is hoped that they would adhere to these recommenda-

tions. Any legislation introduced concerning this subject will be monitored by the responsible CSMS legislative representatives. The complete report outlining the restrictions was distributed to members of the Council. In essence, nurse practitioners, who would have to meet certain educational standards, will be able to prescribe within certain parameters and conditions and would not be able to prescribe any narcotics. It was VOTED to approve the report. It was VOTED that Sullivan and LeShane and the proper CSMS representatives be requested to work to clearly specify the liability responsibility of the advance practice registered nurse in their prescriptive activities.

Edward Kamens, M.D., Chairman of the Governor's Task Force on the Evaluation of Prospective Payment Systems for the State of Connecticut, reported that before filing their annual report, the Task Force had the opportunity to listen to reports from many sources, i.e., the hospitals, VNA, Home Health agencies, etc., all of which are under major stress at the present time because of the great need for extended and home health care. As of the present, there is no factual information on the quality of care and how it has been affected by technology. The report filed is public information and available to any one who wishes to read it.

Dr. Kamens also reported as Medical Director of CPRO, that the quality of care continues to be at a high level. Almost 40% of the charts are flagged and reviewed and the denial rate is at 3-1/2% at the present time. It was down to 2% when there were pre-admission requirements. Most of the shortcomings in the charts reviewed come from documentation. Despite all efforts made, that factor continues to be a problem. There have been 11 sanctions in Connecticut (18 physicians and three hospitals), and there have been no repeat offenders. He urged that quality assurance programs in the hospitals be more diligent in their reviews. The hospitals that have active quality assurance programs are doing an excellent job.

He further reported that once again Connecticut has been selected to participate in a project, this time by American Medical Research Review Organization. The project has to do with small area analysis. This is a study of physician patterns within regions of the state based on the concept of population within certain demographic areas. He urged physicians that, if requested, they participate in this study.

Report of the President

Dr. Zlotzky reported on the following items:

1989 Surveys of Physician and Public Opinion—A letter was received from the AMA inviting state medical societies to participate in the AMA's 1989 surveys of physician and public opinion on a variety of issues related to Medicare, the public image of physicians, peer review, issues in biomedical research, technology and the cost of care. It was reported that although the public survey would be useful, because of other CSMS priorities and

the expense involved, this be considered for future years.

COMPAC—It was reported in the final AMPAC report that Connecticut was rated 19th in the country in all categories with 28% in attainment of membership. More importantly, the percentage of sustaining members in Connecticut is very significant and ranks almost first in the country. Consideration is being given to the publication of a brochure outlining the CSMS position on the many issues that are coming before the legislature.

President's Dinner—The dinner was held on November 9, 1988 and it was very successful. This year section presidents were invited for the first time. The CSMS lobbyist gave an overview of the various issues that would be coming before the legislature, and a list was developed of physicians who would be interested in assisting the lobbyist in testifying at the capitol.

Tort Reform—Attorney Donald Elliott, Professor of Yale on Torts, was selected to pursue the issue of the constitutionality of a cap on non-economic damages. A preliminary report has been received and a meeting will be held on January 13 with the attorney and various CSMS members to review the report.

CMMI Board—At the request of the Council the CMMI Board met on November 7, 1988. The purpose of the meeting was to discuss organizational relationship between CSMS, CMMI and CMIC. Dr. Zlotzky reported that no subsequent decisions were made but were assured that a good faith effort would be made to keep a formal or informal connection between the CMMI and CMIC boards.

At this point, it was decided to discuss Agenda Item No. 10, which had to do with the meeting held between the CMMI, CMIC and CSMS leadership. Sultan Ahamed, M.D. reported that the CMIC Bylaw Committee was going to consider incorporating into the Bylaws representation of CMMI Board Members on the CMIC Board. However, if this was not possible, the CMIC Board would agree to have four members of CMMI Board on their Board. This proposal would have to be done in cooperation with the county associations, because the CMIC Directors are elected through the county association, and there is no direct representation from the CSMS Council. Since the CMMI Board is nominated by the CSMS Council, one solution would be to have the CMIC Board contact the various county associations with representation on the CMMI Board and suggest that the individual serving on the CMMI Board be nominated as the county representative on the CMIC Board. Dr. Zlotzky stated that at the present time there is no guarantee that members of the CMMI Board will become members of the CMIC Board and hoped that a subsequent report would be made to the Council following the meeting of the CMIC Bylaw Committee.

Report on CMMI

James P. Orphanos, M.D., Chairman of the Board of CMIC, reported on the change-over of employees from

CMMI to CMIC. It was stated that as of January 1, 1989, CMIC had 2,400 policyholders which was an increase from 2,375 in October 1988, and represents almost 55% of the market. Staff has been increased and claims-made policies are still the only product available. He also included a report on the assets of the company, the success of the self-study course offered by the Risk Management Committee which gives the physicians a 5% discount on the completion of the course and CME credits, practice seminars, support group sessions and the issue of federal taxes as they relate to insurance companies. It was reported that in late December 1988, a subsidiary of CMIC was formed and will be known as the Professional Liability Services Corporation with headquarters in Wallingford. This subsidiary was formed to insulate CMIC from possible liability for any of the ongoing operations that CMIC has been performing, as well as being able to separate expenses from the main insurance operation.

Report of the Executive Director

Tim Norbeck reported on the following items:

Toll Free Telephone Number—After checking with other state societies, it was determined that those states that did have toll free numbers for their membership did not find it burdensome.

Legislation—1989 appears to be a year of measureless perils with such issues as nurse practitioners, podiatrists and physical therapists all attempting to expand their scope of practice, tort reform, expansion of mandatory assignment and many other items.

HBO Screening of Film on Smoking—It was reported that this film on smoking by C. Everett Koop, M.D., Surgeon General, was excellent and is available to any individual or groups that wish to see it.

Report of the Auxiliary

Mrs. Joan Reed, President of the Auxiliary, reported that the group is having a day at the capitol in March and will be meeting with legislators and lobbyists and attend hearings. They are also working on a possible program for families of impaired physicians. A newsletter depicting some meaningful programs that have been undertaken by the Auxiliary will soon be mailed to non-members with the hope that it will stimulate some interest in membership.

Report of AMA Delegation

Jerome K. Freedman, M.D., reported that in answer to questions as to why AMA did not do something on the RBRVS, it is to be noted that the RBRVS was not an idea of the AMA but was mandated by Congress and the alternative to it was mandatory assignment. In an attempt to cut costs of the care of the elderly, RBRVS was only one of numerous proposals being considered. With one-half million subscribers being added to the Medicare rolls each year, containing costs is not an easy task. The AMA is doing its utmost in working with the other agencies involved in the RBRVS to provide an accept-

able basis for a Medicare indemnity payment system. Drs. Kamens, Van Syckle and Orphanos also reported on the RBRVS, the area capitation system, Registered Care Technicians (RCT's) Antitrust regulations and several other issues. A detailed report had been submitted to all members of the Council prior to the meeting.

M.D. Health Plan Report

Douglas Hayward, President and CEO of M.D. Health Plan joined the Council to give a progress report. The recent stock offering was to increase capital and the number of participating physicians. Although 2,500 physicians had contributed seed money to the CSMS-IPA in 1986, only 1,600 followed through on their commitment to provide the necessary capital for the HMO; thus there was need to continue capitalization efforts. As of January, 1989, there are nearly 12,000 M.D. Health Plan enrollees, and over 4,000 more in the joint venture with Stirling and Stirling, totalling 16,000 patients for our participating physicians already. Mr. Hayward anticipates over 100,000 patient visits in 1989, generating more than \$12,000,000 in physicians fees.

Even after the new stock offering, the need for additional funds was anticipated to maintain the state-required \$1,000,000 reserve. After discussions with the Insurance Department and considering several other options, the MDEC Board chose to raise the remaining capital internally in order to maintain the Society's original objective of total physician control and ownership as established by the House of Delegates. Thus the IPA agreed to levy a membership fee of \$250 for the most underrepresented specialties, and \$500 for others, for this purpose. To address the need for additional physician coverage in some regions and specialties, CSMS-IPA also opened up participation to all remaining CSMS physicians without a stock purchase requirement, through the use of the new membership fee. This further enhances the Plan's marketability and viability, and breakeven is now anticipated in the summer quarter of 1989.

Resolution on Restraints Placed on Physicians by Claims Made Professional Liability Carriers

It was VOTED to refer the above subject resolution, which was referred to the Council by the House of Delegates, to the Connecticut Medical Management, Inc. (CMMI) for study and report. The text of the resolution follows:

"Resolved, That the CSMS Council investigate the possibility of having a reciprocal agreement among professional liability companies so that a physician may contemplate establishment of a medical practice in another state without the purchase of tail coverage, thus allowing physicians more mobility from one state to another; and further be it

Resolved, That the CSMS Council report on this subject to the House of Delegates at its Annual Meeting in May 1989, and that the House of Delegates, at that time,

transmit its action to the Connecticut Medical Insurance Company."

Medical Courtesy Card

It was VOTED to approve a letter presented by Dr. Zlotsky to be sent to editors of all major dailies informing them that CSMS is urging physicians to honor the medical courtesy card beyond the deadline of December 31, 1988 and to advise senior patients who have not applied for their ConnMap card to apply to the Department of Aging immediately. It has come to his attention that many seniors have not had their cards replaced by the State of Connecticut Medical Assistance Program.

It was further VOTED that this information be transmitted to the membership as soon as possible.

Report of AMA Resident Physician Section (RPS)

At the request of the CSMS President that the CSMS/RPS develop a position paper on the resident's work hours in the state of Connecticut, the RPS voted unanimously to recommend to the Council the adoption of Report M of the AMA/RPS with the exception of item #8. It was felt that these principles were consistent with AMA policy and would provide a firm foundation for CSMS policy in discussion of working hours. It was VOTED to approve this report and recommendation and send the report to the Committee on Legislation for their guidance.

Universal Healthcare Insurance System

It was VOTED to refer to the Committee on State-wide Medical Planning for study and report back to the Council at its next meeting, a communication received from Congressman Bruce Morrison's Medical Advisory Committee seeking a proposal from CSMS for the structure of universal healthcare insurance coverage in Connecticut. It was suggested that AMA has information on the issue which may be helpful.

Committee on Public Health

Following discussion of a recommendation to the Council from the Committee on Public Health that the newly added phrase, "Except that such nurse, principal, or teacher may administer aspirin, ibuprofen or an

aspirin substitute containing acetaminophen to any student at such school pursuant to the written authorization of a parent or guardian of such child," be deleted from Section 10-212a, Connecticut General Statutes, as amended by Public Act 88-360, Section 47, it was VOTED to refer the subject to the Committee on State Legislation for action.

U.S. Pharmacopeial Convention

It was VOTED to appoint Michael L. Friedland, M.D., Bridgeport, as alternate delegate to subject convention.

Communication Re: RBRVS

It was VOTED to receive as information a communication from the Medical Center of Northeast Connecticut expressing their strong support for the Harvard Based Relative Value Scale study and to send a copy of the summary report of the AMA which discusses this issue back to this group for their information.

Life Members

It was VOTED to receive as information the following list of Life Members effective January 1, 1989:

William P. Arnold, Jr., M.D., Middlebury (NH)
Henry N. Blansfield, M.D., Danbury (F)
John E. Borowy, M.D., Stamford (F)
Eugene H. Corley, M.D., Bridgeport (F)
John W. Geoghegan, M.D., West Hartford (H)
Walter P. Gerent, M.D., West Hartford (H)
Adrienne M. Krausz, M.D., Westport (F)
John J. McDermott, M.D., Danbury (F)
Alexander Menzer, M.D., West Hartford (H)
John C. Moench, M.D., Guilford (NH)
Hyman Nadel, M.D., Stamford (F)
Richard C. Peterson, M.D., Stratford (F)
Alexander H. Pinkes, M.D., North Branford (NH)
Harold E. Rhame, Jr., M.D., Fairfield (F)
Alan R. Small, M.D., Bridgeport (F)

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on January 11, 1989. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

ALLERGY

Active Allergy Practice in large centrally located Connecticut city with large metropolitan population is available for sale. Also a small office building suitable for one or two doctors available on a sell or rent basis, within easy walking block to hospital or short drive to medical school. Reply to CSMS, AL/VG.

EMERGENCY MEDICINE

Full-time positions in satellite and main emergency departments of JCAH-Approved 380-bed hospital, with residency program. Unique combination of emergency and urgent care medicine. Full hospital emergency department privileges. Paramedic base stations in both facilities. Beautiful shoreline area. Seek EM/FP/IM, BC/BE individual, ACLS, ATLS. ER experience preferred. Highly competitive salary and benefit package. Excellent work schedule. Contact Gordon Van Nes, M.D., Emergency Department, Middlesex Memorial Hospital, Crescent St., Middletown, CT 06457. (203) 344-6691.

Park City Hospital in Bridgeport, CT is seeking full-time Emergency Medicine physician. Twenty-six thousand E.R. visits with Industrial Medical Center in E.R. Active Paramedic Program. Certification in ACLS and experience in Emergency Medicine required. First year compensation \$96,000 with attractive benefit package. Send current CV to: Don Rankin, M.D., Emergency Department, Park City Hospital, 695 Park Ave., Bridgeport, CT 06604 or call (203) 579-5040.

FAMILY PRACTICE

Colchester—BC/BE Family Physician wanted to join busy solo Family Practice. Guaranteed income; good benefits; good coverage and no obstetrics. Potential for partnership in two years. Please send CV to: Dr. Kassem M. Khyber, 79 Norwich Ave., Colchester, CT 06415.

Excellent opportunity to join successful residency trained solo practitioner on the beautiful Connecticut shoreline. Practice and lifestyle of the highest quality in this wonderful family community. Please reply to CSMS, c/o FP/UX.

FAMILY PRACTICE/INTERNAL MEDICINE

Practice for sale. One or two Internists or Family Practitioners to purchase established, active solo Primary Care practice, South Central Connecticut. Stately, spacious offices. Two open staff community hospitals close by. Please apply to CSMS, c/o FP/IM.

MISCELLANEOUS

Retired physician's fully-equipped office, including X-ray, available for immediate rental or sale. Excellent location. Please reply: Judith Turetsky, 496 West McKinley Ave., Bridgeport, CT 06604. (203) 367-9300 for further information.

Plant Physician. The Pfizer Inc. Chemical Production facility in Groton has an immediate need for a Physician to manage the Plant Medical Department which consists of seven employees. Duties include: Providing industrial health services to a facility of 1,800 employees; providing treatment and referral for emergencies and occupational illnesses and injuries; developing innovative medical programs to address employee health and safety issues; providing support in disability return-to-work program, EAP, and case management. The successful candidate will have an MD degree and license to practice medicine; strong management and interpersonal skills; experience in an industrial or military setting a plus. We offer an excellent compensation and benefits package. Please send your resume in confidence with salary requirements to: Mr. Barton S. Finegan, Director of Employee and Community Relations, Pfizer, Inc., Eastern Point Rd., Groton, CT 06340. EOE.

Free-basis, part-time, physicians needed to assist in physical examinations at the New Haven Military Entrance Processing Station. Ideal for retired family practitioners, internists and pediatricians. MD's or DO's must be licensed in a state or territory of the United States, DC or PR. No malpractice insurance needed. \$125.00 to \$150.00 for short morning. Call Dr. Gerhard Mack (203) 787-3823 or write: Commander, New Haven MEPS, 150 Court St., 4th floor, New Haven, CT 06510-2056.

Physician in practice for 30 years seeking part-time employment possibly leading to full-time employment in reviewing charts, hospital records and claims. Write, CSMS, c/o MS/LB.

OBSTETRICS & GYNECOLOGY

Recently trained, solo, OB/GYN, Board Certified seeks BE/BC associate for busy private practice in a beautiful resort community in southern Connecticut. Excellent opportunities for higher education, water recreation, and shopping. Easy access to New York City, Boston, Hartford and Cape Cod. Very stable economy with low unemployment. Would consider two physicians relocating together. Please forward CV to: Stanley P. Solinsky, M.D., 350 Montauk Ave., New London, CT 06320.

OPHTHALMOLOGY

Ophthalmology Practice. Seeking colleague to assume full responsibility soon. Send CV to CSMS, c/o OPH/KN.

K-DUR™ Microburst Release System™ (potassium chloride) Sustained Release Tablets

INDICATIONS AND USAGE: BECAUSE OF REPORTS OF INTESTINAL AND GASTRIC ULCERATION AND BLEEDING WITH SLOW-RELEASE POTASSIUM CHLORIDE PREPARATIONS, THESE DRUGS SHOULD BE RESERVED FOR THOSE PATIENTS WHO CANNOT TOLERATE OR REFUSE TO TAKE LIQUID OR EFFERVESCENT POTASSIUM PREPARATIONS OR FOR PATIENTS IN WHOM THERE IS A PROBLEM OF COMPLIANCE WITH THESE PREPARATIONS.

1. For therapeutic use in patients with hypokalemia with or without metabolic alkalosis, in digitalis intoxication and in patients with hypokalemic familial periodic paralysis.

2. For the prevention of potassium depletion when the dietary intake is inadequate in the following conditions: Patients receiving digitalis and diuretics for congestive heart failure, hepatic cirrhosis with ascites, states of aldosterone excess with normal renal function, potassium-losing nephropathy, and with certain diarrheal states.

3. The use of potassium salts in patients receiving diuretics for uncomplicated essential hypertension is often unnecessary when such patients have a normal dietary pattern. Serum potassium should be checked periodically, however, and if hypokalemia occurs, dietary supplementation with potassium-containing foods may be adequate to control milder cases. In more severe cases supplementation with potassium salts may be indicated.

CONTRAINDICATIONS: Potassium supplements are contraindicated in patients with hyperkalemia since a further increase in serum potassium concentration in such patients can produce cardiac arrest. Hyperkalemia may complicate any of the following conditions: Chronic renal failure, systemic acidosis such as diabetic acidosis, acute dehydration, extensive tissue breakdown as in severe burns, adrenal insufficiency, or the administration of a potassium-sparing diuretic (e.g., spironolactone, triamterene).

Wax-matrix potassium chloride preparations have produced esophageal ulceration in certain cardiac patients with esophageal compression due to enlarged left atrium.

All solid dosage forms of potassium chloride supplements are contraindicated in any patient in whom there is cause for arrest or delay in tablet passage through the gastrointestinal tract. In these instances, potassium supplementation should be with a liquid preparation.

WARNINGS: Hyperkalemia—In patients with impaired mechanisms for excreting potassium, the administration of potassium salts can produce hyperkalemia and cardiac arrest. This occurs most commonly in patients given potassium by the intravenous route but may also occur in patients given potassium orally. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic. The use of potassium salts in patients with chronic renal disease, or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

Interaction with Potassium Sparing Diuretics—Hypokalemia should not be treated by the concomitant administration of potassium salts and a potassium-sparing diuretic (e.g., spironolactone or triamterene) since the simultaneous administration of these agents can produce severe hyperkalemia.

Gastrointestinal Lesions—Potassium chloride tablets have produced stenotic and/or ulcerative lesions of the small bowel and deaths. These lesions are caused by a high localized concentration of potassium ion in the region of a rapidly dissolving tablet, which injures the bowel wall and thereby produces obstruction, hemorrhage or perforation.

K-DUR tablets contain micro-crystalloids which disperse upon disintegration of the tablet. These micro-crystalloids are formulated to provide a controlled release of potassium chloride. The dispersibility of the micro-crystalloids and the controlled release of ions from them are intended to minimize the possibility of a high local concentration near the gastrointestinal mucosa and the ability of the KCl to cause stenosis or ulceration. Other means of accomplishing this (e.g., incorporation of potassium chloride into a wax matrix) have reduced the frequency of such lesions to less than one per 100,000 patient years (compared to 40-50 per 100,000 patient years with enteric-coated potassium chloride) but have not eliminated them. The frequency of GI lesions with K-DUR tablets is, at present, unknown. K-DUR tablets should be discontinued immediately and the possibility of bowel obstruction or perforation considered if severe vomiting, abdominal pain, distention, or gastrointestinal bleeding occurs.

Metabolic Acidosis—Hypokalemia in patients with metabolic acidosis should be treated with an alkalinizing potassium salt such as potassium bicarbonate, potassium citrate, potassium acetate, or potassium gluconate.

PRECAUTIONS: The diagnosis of potassium depletion is ordinarily made by demonstrating hypokalemia in a patient with a clinical history suggesting some cause for potassium depletion. In interpreting the serum potassium level, the physician should bear in mind that acute alkalosis per se can produce hypokalemia in the absence of a deficit in total body potassium while acute acidosis per se can increase the serum potassium concentration into the normal range even in the presence of a reduced total body potassium. The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease, or acidosis requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the electrocardiogram, and the clinical status of the patient.

Laboratory Tests: Regular serum potassium determinations are recommended. In addition, during the treatment of potassium depletion, careful attention should be paid to acid-base balance, other serum electrolyte levels, the electrocardiogram, and the clinical status of the patient, particularly in the presence of cardiac disease, renal disease, or acidosis.

Drug Interactions: Potassium-sparing diuretics; see **WARNINGS**.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term carcinogenicity studies in animals have not been performed.

Pregnancy Category C: Animal reproduction studies have not been conducted with K-DUR. It is also not known whether K-DUR can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. K-DUR should be given to a pregnant woman only if clearly needed.

Nursing Mothers: The normal potassium ion content of human milk is about 13 mEq per liter. Since oral potassium becomes part of the body potassium pool, so long as body potassium is not excessive, the contribution of potassium chloride supplementation should have little or no effect on the level in human milk.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: One of the most severe adverse effects is hyperkalemia (see **CONTRAINDICATIONS**, **WARNINGS**, and **OVERDOSAGE**). There have also been reports of upper and lower gastrointestinal conditions including obstruction, bleeding, ulceration, and perforation (see **CONTRAINDICATIONS** and **WARNINGS**); other factors known to be associated with such conditions were present in many of these patients.

The most common adverse reactions to oral potassium salts are nausea, vomiting, abdominal discomfort, and diarrhea. These symptoms are due to irritation of the gastrointestinal tract and are best managed by taking the dose with meals or reducing the dose.

Skin rash has been reported rarely.

OVERDOSAGE: The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired or if potassium is administered too rapidly intravenously, potentially fatal hyperkalemia can result (see **CONTRAINDICATIONS** and **WARNINGS**). It is important to recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration and characteristic electrocardiographic changes (peaking of T-waves, loss of P-waves, depression of S-T segment, and prolongation of the QT-interval). Late manifestations include muscle-paralysis and cardiovascular collapse from cardiac arrest.

Treatment measures for hyperkalemia include the following:

1. Elimination of foods and medications containing potassium and of potassium-sparing diuretics.
2. Intravenous administration of 300 to 500 mEq/hr of 10% dextrose solution containing 10-20 units of insulin per 1,000 ml.

3. Correction of acidosis, if present, with intravenous sodium bicarbonate.

4. Use of exchange resins, hemodialysis, or peritoneal dialysis.

In treating hyperkalemia, it should be recalled that in patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

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Ataxia Telangiectasia: A Familial Multisystem Disorder

IRA SCHLESINGER, M.D.

ATAXIA telangiectasia (AT) is a multisystem disorder characterized by oculocutaneous telangiectasias, cerebellar degeneration, multiple immunologic aberrations, spontaneous as well as induced chromosomal abnormalities, and a predilection for the development of various malignant neoplasms. Death, which usually occurs in the second decade, is due to infectious complications or malignancy.¹ AT is inherited as a single-gene autosomal recessive trait. Within the United States, the frequency of homozygotes is approximately one in 40,000.² The disease was first reported by Syllaba and Henner in 1926³ and later described by Louis-Bar⁴ in 1941. The term ataxia telangiectasia was coined by Boder and Sedgwick in 1957; a year later they made the first observations on the syndrome's pattern of inheritance, and noted its predilection for children of families of European descent and its lack of sex prevalence.^{5,6}

Ophthalmologic Manifestations

Telangiectasias of the bulbar conjunctiva, most prominent in the medial and lateral canthal regions, usually appear between the ages of two and eight.⁷ These dilated vessels have been shown to be of venous origin and usually remain unchanged throughout life. Most patients manifest the ophthalmologic signs of concurrent cerebellar degeneration such as nystagmus, absence of optokinetic nystagmus, and apraxia of eye movements.⁸

Cutaneous Manifestations

Telangiectasias of areas other than the bulbar conjunctiva do develop later, particularly in sun-exposed regions such as the ears, neck, butterfly area of the face, periorbitally, and in flexural folds of the extremities. These areas usually become involved before the age of ten.⁹ In addition, hyperpigmentation and hypopigmentation, particularly in telangiectatic areas, vitiligo, acanthosis nigricans, café-au-lait macules, seborrheic dermatitis, atopic dermatitis, xerosis, follicular hyperkeratosis, and hirsutism of the arms and legs are all more common in AT patients than the general population. Diffuse premature greying of the hair or white patches of hair, progeroid facies, and sclerodermoid and senescent features may also be seen.^{9,10}

Neurologic Manifestations

The first sign of disease usually becomes apparent at one to one and one-half years of age because of difficulty with ambulation. Initial cerebellar findings may be mild and present only as unsteadiness of gait; however, the ataxia soon worsens and is accompanied by hypotonia, decreased deep tendon reflexes, intention tremor, and dysarthria. The cerebellar dysfunction is usually so severe that ambulation is impossible by age ten. Further neurologic degeneration presents with choreoathetosis, muscle atrophy, and Parkinsonian features of mask-like facies, rigidity, bradykinesia, and constant drooling.⁸ The primary pathologic central nervous system finding is diffuse cerebellar atrophy with a decrease in the number of Purkinje cells.^{11,12}

Immunologic Manifestations

The thymus of AT patients has the appearance of a fetal gland. A modest lymphopenia, cutaneous anergy, a decreased ratio of helper to suppressor T cells and a decreased production of cytotoxic T cells are manifestations of the cellular immunologic defect.¹³ Approximately 70% of patients have a severe deficiency of IgA while approximately 80% have a severe IgE deficiency. Many patients have decreased concentrations of IgG-2 subclass and 80% have an abnormal low molecular weight IgM. The humoral abnormalities appear to be due to an inherent defect in B cells as shown by the fact that even stimuli which do not require T-helper cell activity lack an appropriate IgA response.^{13,14}

Recurrent sinopulmonary infections are usually present by age three; however, oral candidiasis, impetigo, recurrent herpes labialis, disseminated herpes simplex, and chronic active hepatitis have all been reported.^{10,15}

There is significant evidence for autoimmunity in AT patients. Antibodies to IgG, IgA, insulin receptors, and neural as well as thymic tissue have been reported. Anti-mitochondrial, antithyroglobulin, and antismooth muscle antibodies have been reported less frequently.^{8,16,17} Other less conclusive evidence includes the cutaneous findings of vitiligo and acanthosis nigricans.

Laboratory and Associated Findings

A lymphocyte count of less than 1,500 cells/mm³ is

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not uncommon. Hepatic enzyme abnormalities include elevations of alkaline phosphatase, AST, ALT, and lactate dehydrogenase. Greater than 50% of patients have hyperglycemia, usually accompanied by elevated plasma insulin levels and insulin resistance. This effect has been attributed to the circulating inhibitor of insulin receptor binding.¹⁶ Ovarian or testicular atrophy or complete absence of the ovaries is reported, and decreased urinary excretion of 17-ketosteroids is often present.⁷ Accordingly, delayed growth and poor development of secondary sex characteristics are common.

The presence of elevated alpha-fetoprotein (AFP) and carcinoembryonic antigen (CEA) levels is characteristic of these patients. AFP and CEA are not normally present in high levels in adult serum; they are presumably secreted by poorly differentiated, immature cells. The elevated AFP is assumed to be due to the primary disorder rather than to the accompanying features of AT that are known to increase AFP levels such as hepatoma, hepatitis, and testicular or ovarian tumors with embryonic components. The elevated CEA is similarly assumed to be caused by AT itself rather than potential sequelae such as colonic carcinoma or hepatitis.^{8,17}

Chromosomal Abnormalities

Spontaneous translocations of chromosome 14 occur approximately forty times more often in AT lymphocytes compared to normal cells. There is also a marked increase in spontaneous gaps, breaks, and fragments in lymphocyte chromatin of AT patients.^{9,15} AT lymphocytes have been shown to be extremely sensitive to acquired chromatin defects produced by radiation or mutagenic substances such as adriamycin and bleomycin.¹⁸ A defect in the DNA repair process has also been elucidated. When normal cells are irradiated or damaged by mutagenic chemicals, they will enter a period of delay of initiation of DNA synthesis. This is presumably to allow for repair to occur so that chromosomal alterations are not reproduced. AT cells are deficient in this delay of DNA synthesis.¹⁹

This abnormal cellular sensitivity with deficient repair has been demonstrated clinically in the case of a nine-year-old male AT patient being treated with radiation for nasopharyngeal undifferentiated lymphoma. Radiation dermatitis, mucosal ulceration, and severe dysphagia were produced by one fourth of a dose that would be expected to produce such damage in a normal individual.²⁰

Predisposition to Malignancy

The risk for malignancy is 1,200 times greater in AT patients than in the normal population.⁸ It is estimated that 10% of AT patients will develop at least one form of cancer during their lifetime.²¹ Most reported neoplasms have been lymphoproliferative, such as Hodgkin's and non-Hodgkin's lymphoma, as well as lymphoblastic leukemias. Other malignancies such as astrocytoma, medulloblastoma, ovarian dysgerminoma, gastric, renal cell,

hepatic, basal cell, thyroid and pancreatic carcinomas have been reported.^{1,21,22} In younger patients, lymphoproliferative neoplasms predominate while epithelial malignancies are rare. Older patients display more epithelial neoplasms and rarely develop lymphoproliferative disorders. Longer survivors have been noted to suffer from multiple concurrent epithelial neoplasms.²¹

This marked predisposition toward malignancy may be explained by several mechanisms. Spontaneous and induced chromosomal abnormalities with inadequate repair may result in the chance production of a malignant clone of cells. Impaired cytotoxic T-cell immune surveillance could further allow malignant cells to proliferate. Although the spontaneous translocation of chromosome 14 does not in itself explain malignant predisposition, it may be compared to the Philadelphia chromosome and predisposition to chronic myelogenous leukemia.¹⁵ A connection also exists between chromosome 14 translocations and immune deficiency since both IgA and IgE are coded for on this chromosome.¹

Etiology

Because of the multifaceted nature of this disorder, it is difficult to propose one etiologic mechanism to explain all aspects of AT. Certain features, however, can be explained by less encompassing hypotheses.

The defect in DNA stability and repair may explain many AT features including malignant predisposition, neurologic degeneration, telangiectasias, and progeroid skin and hair changes. Because neurologic tissues are not renewable, a defect in chromosomal stability may predispose to premature cell death and tissue degeneration.^{9,15} Cutaneous regions, in daily contact with chemical and radiation insults, demonstrate signs of radiation damage and premature aging.

Autoimmunity may explain some AT features which could not be attributed to chromosomal abnormalities alone. The circulating inhibitor of insulin receptor binding is likely to be the cause of insulin resistance.¹⁶ The antibodies to thymic and neural tissue may be responsible for the poorly developed thymus and for cerebellar degeneration.¹⁷ One function of the normal thymus is to educate T lymphocytes as to recognize self versus nonself tissues. It has been suggested that the aberrant thymus of AT patients may be causally related to the development of autoantibodies.¹⁴

In addition to chromosomal instability and the autoimmunity hypotheses, a defect in mesodermal maturation may be present. Such a defect in tissue differentiation is suggested by the fetal thymus, elevated AFP and CEA levels, and poorly developed ovaries and testes or complete ovarian agenesis.^{1,7}

Heterozygotes

AT heterozygotes are estimated to comprise 1% of the United States population.² Although some heterozygotes demonstrate café-au-lait spots, most carriers do not present with any of the stigmata of AT. The significance

of the occasional finding of café-au-lait macules is unknown since 10% of the normal population have this pigmentation.¹⁰

Shaham et al²³ found nearly normal rates of spontaneous chromosomal breakage in heterozygote fibroblasts, and Chen et al²⁴ found that AT carrier fibroblasts show a radiosensitivity intermediate between controls and homozygotes. Although there appears to be no consistent case for characteristic cutaneous findings or cytologic behavior in heterozygotes, the matter of malignant predisposition is not in question. AT heterozygotes under the age of forty-five are at a risk greater than five times that of the general population for dying of cancer. Greater than 5% of the population who die from a malignancy before age forty-five may be AT heterozygotes. Carriers seem particularly predisposed to ovarian, gastric, biliary, pancreatic, and colonic cancers, as well as leukemias and lymphomas.²

Management

The immunodeficiency component of AT would appear to be the aspect most amenable to medical intervention, but progress in this area has been disappointing. Gamma-globulin has proved of some benefit but only in patients with a specific deficiency of IgG-2 subclass and repeated infections.¹⁴ Levamisole, a drug with both in vitro and in vivo evidence of T-lymphocyte stimulating properties may help in some patients, particularly in reducing bronchial secretions;²⁵ however, large scale clinical trials have not been attempted in AT patients. Thymosin-F5, which reportedly has T-lymphocyte stimulating properties, effects neither laboratory nor clinical improvement.²⁶ Transplantation of allogenic thymic tissue has not resulted in improvement of cell mediated immunity, although recent evidence suggests that a similar procedure when matched for HLA antigens may yield better results.^{14,27}

The most effective therapy to date has been supportive, consisting of physical therapy for recurrent pulmonary infections and appropriate antibiotic treatment for both pulmonary and other types of infection.

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Pancreatic Tuberculous Abscess

ALAN K. MEINKE, M.D.

ABSTRACT—Pancreatic tuberculous abscess is rare and has been reported only in the past five years. An association with the acquired immune deficiency syndrome (AIDS) is suggested. Extensive drainage and appropriate antibiotic therapy is recommended. Intra-pancreatic abscesses should be cultured for *M. tuberculosis* and, if identified, the patient should be studied for human immunodeficiency virus (HIV) infection.

Introduction

Intra-abdominal tuberculosis involving the pancreas is unusual.¹ Tuberculous pancreatic abscess has been described only twice in the English medical literature^{2,3} and this report presents one of only two published survivors.

The data presented in this report suggest that this unusual occurrence may be a result of the weakened immunocompetence characteristic of the human immunovirus syndrome and that such patients may be the harbingers of a recrudescence of unusual and challenging surgical problems reminiscent of the preantibiotic era.

Case Report

A 31-year-old Haitian male who recently immigrated to the United States following a seven-year residence in French Guiana, presented with complaint of two to three weeks of midepigastria pain with radiation to the periumbilical area. He was anorectic and had lost 31 pounds in the last two months. All other gastrointestinal and respiratory symptoms were denied. He specifically denied intravenous drug use, homosexual, or prostitute contact. Physical examination was significant for an oral temperature of 38° C, shotty axillary and inguinal lymphadenopathy, and bilateral gynecomastia. Abdominal examination revealed mild midepigastria and right upper quadrant tenderness without guarding. There was no evidence of hepatosplenomegaly and no palpable mass. Testicular, prostate, and epididymal examination was unremarkable. Initial results revealed a white cell count of 8,400 with normal differential, serum amylase 150

units (0-30), serum lipase 14 units (4-24), hemoglobin 9.5 g, and sedimentation rate 92mm per hour. Multiple blood cultures were negative and hepatitis B surface antigen was nonreactive. Abdominal ultrasonography showed no abnormalities. His chest film revealed a right paratracheal mass. A computed tomographic scan of the abdomen (Figure 1) revealed a lobulated retrogastric, mixed attenuated, noncystic mass with enlarged periaortic lymph nodes and splenic enlargement. Reticulocyte count was 0.6, serum iron 7 µg/dL (40-135), total iron binding capacity 164 µg/dL (280-400), and alkaline phosphatase 91 µ/L (90-282). Morning and afternoon cortisol levels were within normal limits. Intradermal PPD was negative. Beta subunit of human chorionic gonadotropin, alpha-fetoprotein, liver function tests, alpha₂ globulin, and urine analysis were all within normal limits. With the presumptive diagnosis of a malignant lymphoma or retroperitoneal tumor, the patient underwent an exploratory laparotomy. A large mass of firm consistency was identified involving the pancreas and both the transverse colon and small bowel mesenteries. Frozen section examination of numerous mesenteric lymph nodes revealed noncaseating inflammation. On freeing the posterior aspect of the stomach from the mass, approximately 200mL of green, purulent material drained from within the pancreatic tissue. The area was widely drained and the patient was placed on broad-spectrum antibiotics. Postoperatively, he remained febrile and developed acute respiratory distress syndrome requiring ventilatory support. When microbiologic evaluations of pancreatic purulence revealed *M. tuberculosis*, he was treated with ethambutol, rifampin, isoniazid, and pyridoxine. His fever rapidly fell to normal and he was discharged from the hospital on the 20th postoperative day. He returned to full activities and continued to improve while being followed in the pulmonary outpatient clinic. Because of the unusual presentation of tuberculosis, permission was granted to test for HIV. Serum was found to be positive for antibodies using the immunoabsorbant assay. T4 cells were absent. A repeat abdominal CT scan revealed resolution of the pancreatic mass (Figure 2). Six months following hospital discharge, the patient was readmitted with disseminated cryptococcus and expired. Blood,

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cerebrospinal fluid, and bone marrow cuttings demonstrated *C. neoformans*.

Discussion

Duodenal obstruction resulting from peripyloric lymphatic tuberculosis is well described^{4,5,6} as is biliary obstruction from tuberculous adenitis.⁷ Autopsy studies of miliary tuberculosis report pancreatic involvement ranging from 2.7%¹ to 20%⁸ but clinical presentation of focal pancreatic tuberculosis is distinctly unusual^{9,10,11} and tuberculous pancreatic abscess has been described

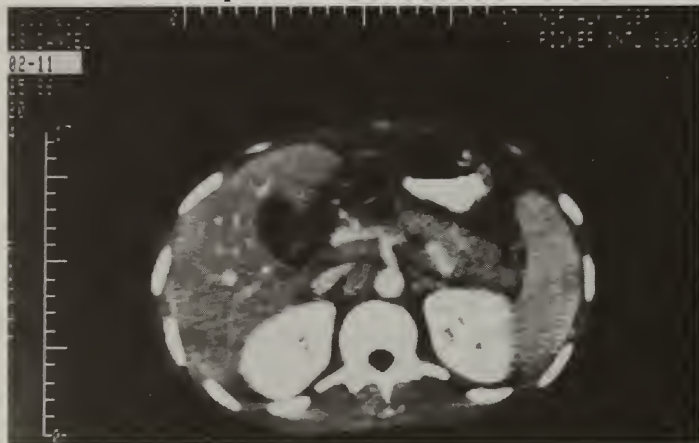


Figure 1

Abdominal CT scan without intravenous contrast revealing a lobulated retrogastric mixed attenuated mass, enlarged periaortic lymph nodes, and splenic enlargement.

only twice in the medical literature.^{2,3} Both patients have presented since 1982 but before accurate tests to detect HIV were available. Because of this, neither was tested for HIV.

Stambler³ reported a 33-year-old Haitian woman who presented with a fever, weight loss, weakness, and splenomegaly. As with our patient, an extensive work-up, including sputum and blood cultures as well as PPD skin testing, failed to suggest a tuberculous etiology. A CT scan of the abdomen revealed a pancreatic mass, and eventual exploration of the pancreatic head resulted in drainage of a tuberculous abscess. Despite proper antibiotic therapy, the patient developed postoperative *Klebsiella* pneumonitis and expired.

Three years later, F. deMiguel published a case report³ of a 51-year-old Caucasian man with similar complaints of fever and weight loss. Investigation failed to reveal the etiology of his fever. Exploratory laparotomy revealed a pancreatic abscess that was widely drained. When conventional antibiotics failed to reduce his fever, the possibility of tuberculosis was entertained and the subsequent treatment with appropriate antibiotics resulted in clinical improvement. Follow-up CT of the abdomen showed resolution of the pancreatic abscess with new onset of intra-abdominal lymphadenopathy.

Our patient is the third to be reported with a pancreatic tuberculous abscess. The preoperative diagnosis was intra-abdominal abscess or lymphoma. At laparotomy, the pancreas was firm to palpation and the diagnosis of pancreatic carcinoma was assumed. On mobilization of

the pancreatic head, purulent material drained from within the pancreatic parenchyma. Finding acid-fast bacilli on smears secured the diagnosis.

All three cases of pancreatic tuberculous abscess have been reported within the past five years. Widespread ability to detect HIV has developed only recently and its detection in our case suggests a correlation between this unusual presentation of tuberculosis and adult acquired immunodeficiency syndrome (AIDS).

It has been well documented that tuberculosis may be the initial presenting manifestation in many patients who eventually demonstrate infection with the AIDS virus.¹⁷ Compared with the general population, there is a hundred-fold increase of tuberculosis among AIDS patients.¹⁸ This is particularly noted among Haitians with AIDS.^{12,13,14} Although this increase is primarily due to *M. tuberculosis*, infection by the more unusual *M. intracellulare* and *avium*,^{14,15,16} have also been identified.

Many individuals with AIDS and tuberculosis present with overwhelming disease in advanced stages. In a recent series¹⁶ of 136 patients with AIDS, 29 had severe and unusual manifestations of tuberculosis. This group was characterized by a lack of reaction to PPD skin testing and poor granuloma formation. Of these 29 patients, 16 (55%) had disseminated disease and 21 (62%) presented with extrapulmonary disease. The national 1980 tuberculous extrapulmonary rate was 14.2%. Extrapulmonary tuberculosis has risen 10% between 1980 and 1984,¹⁶ likely reflecting the rising prevalence of AIDS in the population.

Poor granuloma formation and poor reaction to intradermal PPD testing have been noted in other studies of tuberculosis in AIDS populations.¹⁷ This delays recogni-



Figure 2

Abdominal CT scan showing resolution of pancreatic abscess.

tion of infection and allows progression of the disease. As in the era prior to successful antibiotic treatment, these advanced forms of tuberculosis can present as surgical challenges both in diagnosis and treatment.

It has been estimated that over 2 million Americans currently harbor HIV.¹⁹ As clinical detection becomes more available, we anticipate its correlation with tuberculous abscess will be more clearly defined.

Until this correlation can be demonstrated, we suggest that cases of pancreatic abscess or any unusual intra-abdominal abscess be addressed with a differential diagnosis which includes both tuberculosis and AIDS. Patients presenting with unusual or aggressive manifestations of tuberculosis should have serologic testing for AIDS and be followed for long periods of time to detect subsequent opportunistic infections. Appropriate protective measures should be instituted.

When intra-abdominal tuberculosis and AIDS are identified, conservative drainage and appropriate chemotherapy is recommended over resection. Results in our case and others,¹⁴ support this recommendation.

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Internal Carotid Artery Aneurysm: A Vascular Manifestation of Type IV Ehlers-Danlos Syndrome

STEVEN T. RUBY, M.D., JONATHAN KRAMER, M.D.,
SUZANNE B. CASSIDY, M.D. AND PETROS TSIPOURAS, M.D.

ABSTRACT—Aneurysms of the distal internal carotid artery (ICA) can be difficult to manage. When seen in a patient with Ehlers-Danlos Syndrome, type IV (EDS-Type IV), the complexity of the problem is greatly increased. Proximal ICA ligation in the presence of an intact circle of Willis and adequate collateral circulation is a reasonable and safe approach. We recommend the liberal use of duplex scanning and intravenous digital angiography in patients with EDS, and plan to use these techniques to follow the small, asymptomatic, right ICA aneurysm in our patient. If the aneurysm rapidly grows or becomes symptomatic, treatment may require proximal ligation with extracranial-intracranial bypass. Understanding of the basic defects associated with EDS-Type IV will make the management of patients with vascular complications more safe.

Introduction

THE Ehlers-Danlos syndrome (EDS) is a group of heterogeneous genetic disorders of collagen, which in some forms is manifested by complex and often life-threatening vascular complications. Knowledge of the various types of vascular lesions seen in EDS will aid the vascular surgeon with the management of patients with this rare set of disorders. EDS is currently divided into eleven different types based on biochemical criteria and phenotypic expression.¹ Several previous reports in the literature provide excellent documentation of the arterial complications, but lack biochemical verification of the specific subtype of EDS. Recent experience with a patient at the University of Connecticut Health Center with well-documented EDS-Type IV prompted this case report and a review of the vascular complications of EDS.

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Case Report

K.D., a 22-year-old female with EDS-Type IV, was referred to the vascular surgery clinic at the University of Connecticut Health Center with a five-month history of transient left eye blindness. The episodes occurred several times per week, lasted from one to ten minutes, and were described as gradually increasing darkness until there was no vision at all. Pain in the left eye would often, but not always, accompany these episodes, and her vision was always normal between episodes. She denied any other neurological symptoms. A diagnosis of EDS-Type IV had been made clinically at age 16 and was confirmed biochemically at age 20, when cultured fibroblasts from a skin biopsy failed to secrete Type III procollagen.¹ She had a history of varicose veins, bruised easily, had thin skin, and hyperextensible joints. At age 20, she had an uneventful pregnancy and cesarean section delivery of a female infant. Previous publications detail her biochemical findings¹ and pregnancy management.² Her mother had EDS and died suddenly at home at age 41. Her sister also has EDS.

Physical examination was remarkable for thin skin, visible subcutaneous veins, hyperextensible small joints, and normal appearing scars. There were no cervical bruits, and her neurological examination was normal. Laboratory tests were normal, including bleeding time and coagulation studies. Ophthalmologic evaluation was normal. Noninvasive evaluation of the extracranial vasculature included OPG-GEE (oculoplethysmography-GEE), which demonstrated a hemodynamically significant stenosis in the left internal carotid artery (ICA). A hemodynamically significant lesion in the distal ICA was seen with ultrasound spectral analysis. Real-time ultrasound visualized soft plaque at the mid left ICA.

Because of continued symptoms and agreement between two noninvasive modalities about the presence of disease in the left ICA, the patient underwent digital intra-arterial angiography without incident (Fig. 1). A large aneurysm of the distal ICA was demonstrated.

Approximately five weeks after the initial presentation she was operated upon for exploration of the left ICA under general anesthesia. A five-minute "test" clamp was performed without changes noted on the EEG monitor.



Figure 1

Lateral carotid angiogram: There is a large pseudo-aneurysm of the distal aspect of the cervical left internal carotid artery, with intimal irregularity and/or clot within it. The middle segment is markedly narrow and smooth.

The left ICA was then ligated just distal to the carotid bifurcation. Her postoperative course was uneventful, and she remains asymptomatic and is not taking anti-platelet agents.

Discussion

The phenotypic appearance of patients with EDS was first described in 1682 by VanMeckern.³ Ehlers in 1901⁴ and Danlos in 1908⁵ further refined his description and made note of the three classic features (skin hyperelasticity, skin fragility, and joint hyperextensibility) of the syndrome which now bears both of their names. It has subsequently been determined that several genetically distinct conditions result in this clinical syndrome, some inherited as autosomal dominant, some autosomal recessive, and one X-linked.¹ The phenotypic expressions of this disorder of collagen metabolism include the three classic features noted above and may also include "cigarette paper-thin" scars, multiple ecchymoses, subcutaneous pseudotumors, and life-threatening abnormalities of the cardiovascular system.

In only four of the eleven types of EDS has the actual biochemical defect been elucidated.¹ Type IV is the rarest and perhaps the most severe form of EDS and may be inherited as an autosomal recessive or dominant. The underlying abnormality in Type IV EDS is a defect in the synthesis, assembly, or secretion of Type III collagen.⁶ The structural integrity of arteries and veins and of hollow viscera depends on the presence of Type III collagen and is therefore lost in EDS because this type of collagen is absent or present in reduced amounts.⁷ Presumably this is the pathophysiologic basis for vessel wall dissection, aneurysm formation, and rupture. Bleeding is

a common problem in patients with EDS and can be life-threatening despite normal platelet function and number as well as normal levels of coagulation factors. Type III collagen is the predominant form of collagen in the subendothelial level of blood vessels and is important in promoting platelet aggregation.⁸ Poor hemostasis and possibly vessel rupture may result from the inability of the defective collagen to promote platelet interaction with the vascular endothelium. For this reason, DDAVP (1-desamino-8-D-arginine vasopressin) had been given to our patient during her cesarean section in an effort to promote this interaction.²

There have been a number of reports of unusual, complex, and often fatal vascular disorders in patients with Type IV EDS, which has been referred to in the past as the arterial or ecchymotic type. Of note is that many patients with Type IV EDS have few of the outward phenotypic expressions of the disease because of limited skin and joint involvement. The first report of a fatal vascular complication of EDS appeared in 1960.⁹ Imahori et al reported the first association of multiple congenital aneurysms and EDS in a 42-year-old patient, who died as a result of intra-abdominal hemorrhage.¹⁰ Pathological evaluation of this patient at autopsy revealed abnormal appearing collagen fibers in the media of medium size (muscular) arteries. Other reports of arterial pathology in EDS describe an irregular thinning of the media of large arteries with an obliteration of the internal elastic lamina,¹¹ as well as a separation of the elastic lamina in the inner third of the media with increased proteoglycans.¹² There have been numerous vascular lesions reported in patients with Type IV EDS. These include: dissection of the thoracic aorta, aneurysms of the abdominal aorta, hepatic, renal, subclavian, splenic, and iliac arteries, rupture of the aorta, subclavian artery, and the hepatic artery within the liver, as well as varicose veins.^{11,12,13,14,15,16} Arteries are often of normal size and do not have to be aneurysmal prior to rupture.

Cerebrovascular complications of EDS are well known. There have been several reports of carotid-cavernous fistulas in the literature.^{17,18} Intracranial aneurysms have been described as well.¹⁹ We believe this is the first well-documented case of an aneurysm of the cervical segment of the ICA in the setting of Type IV EDS. Because the lesion extended to the bony canal of the skull, it was felt that a repair or excision in the usual fashion could not be done. Proximal ICA ligation was done, and this has been a common procedure for intracranial pathology in EDS. Ligation was undertaken in an effort to treat her frequent episodes of amaurosis fugax, as well as to try to prevent rupture of the aneurysm.

A variety of technical recommendations have been made by surgeons and radiologists with experience in managing the arterial complications of EDS. Angiography can be dangerous in patients with EDS and has been associated with vessel wall dissection, perforation, and death. Invasive diagnostic procedures should be

done only when all available noninvasive techniques have been truly exhausted. Intravenous digital technique may be the safest and most efficient way to assess arterial pathology in EDS. Aortic rupture in most cases will be a lethal event; however, patients presenting with cardiovascular collapse and acute abdominal pain should be explored because of the possibility of branch disruption (ie, splenic or iliac), which may be controlled with ligation. The simple application of ligatures may be difficult, and as noted by Barabas, direct suturing may not be possible.²⁰ False aneurysms of the extremities have been controlled with ligation.²¹ The use of native vein for bypass should probably be discouraged because of the tendency to varicose vein formation. Hematoma formation in the wound is common.¹³

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The Epidemic Hysteria Dilemma

MATTHEW L. CARTTER, M.D., PATRICIA MSHAR AND HAROLD BURDO, MPH

OUTBREAKS of illness among schoolchildren can be dramatic and perplexing events for school officials, physicians, and public health professionals. Such outbreaks can pose pitfalls for their investigators, especially when the diagnosis of epidemic hysteria is considered. In 1986, we were asked to investigate an outbreak of possible foodborne illness in sixth-grade students at a school in Connecticut. The outbreak occurred while the students were practicing the school song for graduation ceremonies. At least 39 of the 72 students became ill over a half-hour period. Symptoms most frequently reported were abdominal pain (74%), headache (67%), sweating (64%), weakness (62%), and dizziness (54%). The physical examination findings were normal and symptoms resolved for most within three hours of illness onset. Three teachers who had eaten food served at the party became nauseated later in the afternoon. Further questioning suggested that their illnesses may have been associated with the perception of having been exposed. The epidemiologic investigation revealed that students who had eaten chocolate cake at the graduation day lunch were more likely to become ill than students who did not (relative risk = 2.0, 95% confidence limits = 1.3 to 3.0, $P < .01$). The review of food-handling procedures and laboratory tests of the cake and other foods failed to identify problems with preparation or a bacterial or chemical cause of illness.

The rapid onset of illness and resolution of symptoms and the absence of vomiting and diarrhea made it difficult to attribute this outbreak to a known bacterial or toxic cause of food poisoning. Still, we felt an obligation to rule out possible physical causes of the outbreak. Because the outbreak had some of the features of mass psychogenic illness, our "in-house" assessment was that much of the illness may have been due to epidemic hysteria.¹ Of particular importance was the lack of evidence of a continuing or more widespread threat to public health. This was the key message that we wanted to convey to the public.

The press reported that we were considering the diagnosis of epidemic hysteria on the same day that students were given the food history questionnaires. Our unantic-

ipated public discussion of this diagnosis was done largely without the results of the data analysis, which was completed a week after the outbreak. Despite our assurances that the symptoms of psychogenic illness were real, some parents insisted that we had accused their children of faking symptoms and that a "stigma" had been put on their children. Levine² has suggested that the treatment of mass hysteria should include informing patients and the public of the suspected psychological cause of the illness. Our experience suggests that with such notification, the diagnosis can become part of the problem and the public relations aspect of an investigation can easily become the primary focus of activity.

Differentiating a foodborne outbreak from epidemic hysteria has important implications for clinical treatment and for public health control measures. If done early enough, an epidemiologic investigation can help focus control measures, especially during a foodborne outbreak. If done after an outbreak is over, an epidemiologic investigation can help in the review of professional decisions. Our investigation revealed an association between eating chocolate cake and illness, an association that we found difficult to explain and that was for us analogous to finding an unexpected cause of death at autopsy.

Some authors have cautioned against extensive epidemiologic investigations when epidemic hysteria is considered because of the tendency of such investigations to prolong public concern.^{1,3} Clearly, the public relations aspect of the investigation must be handled carefully to avoid public misunderstanding. In retrospect, psychiatric consultation might have been helpful in managing the outbreak, both to examine children for positive psychologic data and to endorse the diagnosis of epidemic hysteria. Outbreaks similar to the one that we investigated happen often enough that clinicians and public health professionals need to become better acquainted with the science and art of dealing with epidemic hysteria. It is hoped that knowledge and experience once shared will lead to better ways of managing such episodes.

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Legal Aspects of Employing “Counselors” in a Clinical Practice

ROBERT S. WALZER, M.D., J.D.

ABSTRACT—With the increasing reliance of the medical profession upon nonlicensed counselors as employees or associates for facilitating psychosocial, rehabilitative, and various other services or guidance to patients, there is a parallel increase in liability exposure. Even if the counselor is not directly employed by the professional, so that the tort doctrine of *respondeat superior* would not pertain, other ties could cause either a direct agency or an ostensible agency doctrine to attach. This is so even if a referred patient merely had reasonable cause to (mis)understand an apparent agency relationship. Billing must be precisely worded and coded. There are ethical, medical, and legal responsibilities to screen applicants and to monitor, formally supervise, and record a counselor's work. Standards of care are unclear or untested. Referral of a troubled patient to an uncredentialed assistant may convey trivialization to the patient; however, beware misrepresentation of expertise. Failure to diagnose underlying disorder is a risk. Protocol agreement defining the scope of the relationship and the scope of practice may help limit liability. Any economic arrangement or prescription of a particular counselor's services can lead to the doctor's being joined in a suit, especially because of the “deep pocket” theory. Clarification of liability coverage is therefore prudent.

THERE is a trend in medical, psychiatric, and clinical psychology practice toward increasing reliance on nonlicensed staff for the counseling of patients for mental health, family or school problems, nutritional needs, or exercise and rehabilitation, and so forth. Where the licensed professional shares, refers, or supervises cases with nonlicensed counselors (used as a generic), such collegial or employing physician or clinical psychologist has a number of duties, obligations, and liabilities to these patients that are more complex than they seem to many practitioners. Delegation to unlicensed agents presents a threat to the caliber of service offered, and if

unsupervised and unregulated, it can undo the protections provided the public by requirement of licensure. Cases of such failure injurious to patients have appeared at the regulatory agencies. In addition, some clinicians and provider entities rent office space to, and/or form an actual or seeming (apparent or ostensible) relationship with, a “counselor” who is not governed by membership in, or by the standards of, a licensed profession. Tort law doctrines of vicarious liability are, today in this litigious world, understood by most clinicians. However, statutes and regulations often come to bear, and the latter are frequently scattered, not easily located, and not commonly known even within the legal profession. There are also a number of not sufficiently well known professional and ethical standards issued by societies and organizations that could certainly be introduced in litigation by a well-prepared attorney seeking to define a standard of care. (These will be discussed in detail in a subsequent article on mental health-care entities.)

The most common reason for which the licensing board becomes involved is related to questions over third-party billing by the professional for such counseling actually rendered by an employee or supervisee. But the billing issue acts as a gateway to many other questions of liability that could support a possible cause of action where a patient or counselee claims injury caused by allegedly negligent care.

Case example: A physician referred a child with school problems to the counselor whom he employed for such purposes. The employee had professional training but had chosen not to seek a license. Billing was done by the physician on his letterhead, the charge simply attributed to “visit” or “counseling.” After a number of twice-weekly, and later weekly visits, the third-party payor refused further payments on the ground of noncovered service, and asked that the physician be more specific as to the service given: definition, identity of the person actually doing the counseling, and a diagnosis for which it was rendered. The patient's parents sent an inquiry and complaint alleging unethical and substandard treatment to the Department of Health Services, and an investigator found insufficient supervision of the counselor, insufficient feedback to the doctor by the counselor, and

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unclear if not evasive billing. Ultimately, a case was opened that covered these issues as well as questions of the referral pattern between the two professionals, their economic arrangements, supervisory and diagnostic procedures in this and all other cases shared by the two, and ongoing medical observation of a shared patient who is taking medication and/or has a physical illness. The case was settled between the physician and the Department with an agreement for compliance with terms and guidelines that are discussed below.

Billing

Billing practices involve matters of ethics, regulations, policy, and third-party payor requirements. Concisely, these add up to the following: a licensed physician billing in his or her name for *medical* services must personally have provided them, unless the services were performed by a nonlicensed delegate "directly controlled by" the physician, in the physician's presence, for a relatively minor or delegable procedure.¹ The "presence" of the physician may be somewhat broadly defined within standards of good care, and thus it does not necessarily mean that the physician must be in the same room or observing the activity, but, at least according to regulations (noted below) of the Department of Income Maintenance (DIM), within five to 15 minutes away. It is generally agreed that counseling is not a relatively minor procedure. Therefore, the delegated counseling should be so described on bills for services on the physician's letterhead, with the name of the counselor and the number and duration of visits specified. Omission of these data regarding the counselor's role in services billed by the professional is considered erroneous or evasive, and might imply fraud or misrepresentation to the billed party.^{2,3} An essentially identical statutory provision applies as well to psychologists in Connecticut.⁴ The Board of Examiners of Psychologists has ruled the above provisions applicable to clinical psychology, and further ruled that the name of the delegated assistant must appear in any bill or "listing of services performed. . . ."⁵ Aetna, it may be noted, does not hold these forms of mental health counseling as exclusively or particularly medical and Aetna would not reimburse for these, as of April 1988, but The Hartford would cover "medical" counseling. Medicare would "downcode" if uncertain.

While a licensing board or department does not monitor the licensed professions for the protection of insurers, questions of misrepresentation, lying and fraud, moral turpitude, and unethical conduct inconsistent with the practice of medicine or psychology are within the jurisdiction of the medical quality assurance divisions of the departments, and they may investigate and prosecute. In a case involving a psychiatrist who employed a licensed psychologist and a number of nonlicensed counselors but who billed all patients alike as having psychotherapy at private psychiatrist rates, the DIM ruled that the practice was run as a clinic and should bill at clinic rates. The investigation had found that the psychiatrist had

never seen many of the patients who had come to his practice and who were seeing counselors exclusively; further, the charts showed no evidence of psychiatric supervision or control. The ruling noted that a licensed, employed psychologist did not require the amount of supervision that the unlicensed personnel should be given. The psychiatrist was fined and required to reimburse Medicaid for overpayments.⁶ Medical services of a physician may include assistance for the doctor, but this must be under the doctor's "personal supervision," and the physician must actually see the patient and have actually performed an examination and rendered a diagnosis; furthermore, "[t]he physician must be on the premises at all times and immediately available, meaning within five minutes."⁷

The DIM, under Medical Services Policy Regulation 183 I. III. a.-c., provides payment for a psychologist's services only if those services were rendered personally by the psychologist.

It should be remembered that an exclusive referral pattern is unethical and suggests negligence in proper referral care.

Fee-splitting is also unethical, and "rent" paid by a counselor that is derived from a percentage of fees generated by the referrals is splitting. An hourly rent, however, may escape this categorization, but it would be advisable to obtain a ruling on this from the appropriate department and professional association for the particular jurisdiction.

Supervision of a Counselor Whether or Not an Employee

A physician or psychologist is expected to oversee, train, and supervise his or her staff, and to function under and within the laws and ethics that govern. It is improper and unreasonable to expect any greater professional capabilities of staff than can be expected by virtue of education, training, and experience.

But what is "supervision?" What would it mean as the basis for a reasonable and prudent standard of care under the law? In everyday practice, one might be able to "oversee" in a rather cursory or unstructured style that has no formalized routine. However, supervision of an assistant is generally understood to be a more formalized activity and process than mere oversight; the assistant's work must be "under the physician's supervision and control," with the doctor overseeing and participating in the assistant's work, and with review on a "regularly scheduled basis."⁸ We come to realize and recognize that cases under the attention of the counselor need to be discussed and direction to be given as medically indicated, and that some sit-down discussion between the licensed, responsible professional and the employed or otherwise associated counselor is a reasonable expectation.

Guidelines do not seem to exist regarding the amount of time to be given to supervisory discussion of a case in these circumstances any more than the time to be given

to patient visits, but diligent and prudent care and attention to the patient's needs, and thus to the work of the counselor, are reasonable expectations. This also subsumes adequate communication by the clinician to the counselor of pertinent medical and social circumstances, in order for the counselor to carry out his or her role safely and effectively, and with due regard for the counselee's health and abilities.

The legal standard applied to the professional is that of the reasonable, prudent physician or psychologist; a specialist would be held to standards for the specialty. Thus, a psychiatrist or psychologist would likely be held to stricter standards regarding supervision than others because supervision has always played a key role in their professions and in casework as well.

While feed-back of information from the counselor to the professional may occur during such supervisory discussion, important material that may be relevant to the patient-counselee's medical or general care or prognosis should be communicated and documented contemporaneously. Supervision should not be preempted by mere nonsupervisory reportorial communication. For legislative intent here, recall the Conn. Gen. Stat. §20-12a requirement of supervision of a physician's assistant including "regularly scheduled" review of the assistant's practice and the physician's "continuous availability" even through "radio, telephone or telecommunications. . . ." The physician/counselor relationship would likely be held to at least the same standard.

In fact, the physician or psychologist is advised to have a formal supervisory protocol for regularly guiding and overseeing the work of the counselor (who is his or her agent) and to assess for possible inadequacy of care (for instance, development of problems beyond the scope of the counselor's expertise or even the physician's or psychologist's expertise, raising the indication for referral to a more appropriate treatment). While such a protocol will serve to help the parties to accept the importance of and to institutionalize the activity, it also documents the participants' recognition of its place in the conscientious care that they provide.

Through a "scope of practice" agreement with the counselor the professional might attempt to contain the area of risk exposure. This protocol would define the work, duties, and objectives of the counselor as accepted and approved by the physician. While this definition may be less tenable or defensible than for a licensed nurse or other professional employee, and even for a certified and statutorily defined (but not licensed) physician assistant, it would possibly offer some protection from allegation of injury attributed to treatment that exceeded the limits of the protocol.

Vicarious Liability

The physician or licensed professional has continuing responsibility for the quality of care rendered to patients by the counselor. In a sense, the professional is treating

the counselee through the agency of the counselor; this doctrine is true for the psychiatrist or psychologist, long accustomed to working with or in the role of a supervisor, but it is no less true for the obstetrician or nephrologist who works with (or through) a counselor (or agent). Under tort law, the employer is responsible for the injuries caused by negligence of an employee acting within the scope of her duties. Moreover, a doctor could be held liable for negligent conduct of an employee or associate if the injured party had reasonably believed, or been induced to believe, that the doctor had been in control of the conduct of the employee or associate: this is called the doctrine of ostensible or apparent agency.⁹ The unlicensed counselor-employee cannot act independently, unlike a licensed nurse in some circumstances. Because the doctor represents a richer lode than a nonprofessional assistant, patients alleging harm by the latter will seek to target the "deeper pocket" in litigation.

Misdiagnosis of and/or failure to treat an underlying affective disorder, suicidal potential, or physical disease through inadequate history-taking or diagnostic ineptness would be the likely sources of litigation. If sufficient progress is not made within a reasonable period of counseling, the professional should review the case and consider referral to a specialist, and discuss alternative care with the counselee, to avoid prolongation of psychic distress.

Where a patient with the expectation of standard medical care comes to a physician's office complaining of "bulimia," for instance, should the receptionist route the patient to the nonlicensed counselor who was trained in pastoral counseling and is employed by the doctor, and the patient never to see the physician? Not only may this be misleading to the patient, but the physician is being negligent. Both the patient's well being and the physician's license would be in jeopardy.

Quality Assurance, Records, and Documentation

It is prudent (it is actually a legal duty) to check the credentials and references of the counselor to be employed, to communicate with prior employers, and to be alert to indications of possible substance abuse. These are all the more critical because nonlicensed counselors are not monitored by licensing agencies, obviously, and may not belong to any professional societies; therefore, these cannot provide a file review for complaints.

The counselor-employee should regularly enter notes into the patient's charts or records, and the physician's entries should indicate that he or she is aware of these notes and the patient-counselee's status. The counselor should also keep more detailed records or process notes, especially those too confidential or irrelevant for the medical chart, but reviewable in supervisory discussion.

Incidentally, in some jurisdictions, mental health records or communications to a generic psychotherapist enjoy a privileged and confidential status that medical records do not, at least if the counselor fits the statutory

definition of psychotherapist, psychologist, or psychiatrist. Connecticut's statutes convey this privilege exclusively to patient communications to psychologists and psychiatrists.¹⁰ Remember that a physician-patient privilege does not exist at common law and has not been legislated in Connecticut and many other states. In Connecticut, while statute and psychiatric authorities hold that only a licensed psychiatrist provides *psychiatric treatment*^{11,12} and Conn. Gen. Stat. §20-187a reserves *psychological services* to licensed psychologists, other professions lay claim to *psychotherapy*, arguing that it can be provided by an array of therapists and counselors. However, the Connecticut Board of Examiners of Psychologists and the Connecticut Attorney General, in their statements cited above, are of the opinion that only licensed professionals can perform "psychotherapy." The Uniform Rules of Evidence, procedural rules of court governing the production of evidence and adapted for use in a number of state court systems, require, in Rule 503, that a "psychotherapist," for the sake of privileged communications, be either a licensed physician or psychologist, but confidentiality is extended to communications made for purposes of diagnosis or treatment to "persons" participating in the process under the direction of the physician or psychologist. Therefore, it is arguable in some jurisdictions and certain in others that communication to a nonlicensed counselor is not protected by statutory privilege, especially if required supervision, direction, and control are not provided. Should, at least, certain patients who may possibly and reasonably be relying on it be timely informed of the possible lack of such privilege?

Of course, there is a duty to not treat, directly or through an agent, illness or disorder which is not encompassed by the education, skill, or training of the clinician or the agent, with the possible exception of stop-gap emergency care. It is advisable that patients with possible or actual active or on-going organic mental disorders, major depression, or suicidal or assaultive potential be referred to the most appropriate professional diagnostic and treatment resource. Thus there is a duty first to evaluate and diagnose every patient prior to referral to the counselor, and to rule out underlying medical disease and disorder beyond the expertise of the clinician or counselor. A pediatrician's specialty would reasonably include nutritional and dietary expertise, and a nonlicensed nutritionist's counsel could be a service delegated by the doctor under his or her direct supervision and control. In this era of psychopharmacotherapy and complex testing for affective and other psychiatric disorders and their consequences, it could be questioned whether the pediatrician could provide adequate supervision of a mental health "therapist's work. . . ."¹³

The public is free to seek counseling or treatment from unlicensed providers. The Department of Health Services, which regulates licensed health-care providers, would not have jurisdiction, and statutes and regulations regard-

ing the professional conduct of licensed individuals and entities would not pertain. If a question arose as to quality of care, the client would have to turn elsewhere in the law. But when a licensed physician, psychologist, or clinic is the employer of such nonlicensed staff, the license holder, under the law, directs the treatment and is expected to conform to the letter and intent of the law.

Promises, Implied Promises, and Misrepresentation

A physician's assistant may be trained for certain procedures and responsibilities, which presumably may include counseling. The physician or psychologist has a duty not to misrepresent services provided and not to hold out as being rendered services not in fact provided. It is wise to avoid even misleading vocabulary or the suggestion that the patient being referred to the counselor or assistant is to receive the same or the equivalent of treatment that would be rendered by a more trained or certified professional such as a licensed therapist, physician, or clinical psychologist. The author has heard countless examples of referrals to an employed or associated counselor with words such as, "Mrs. X will help you in half the time and a tenth of the cost that the psychiatrist would run up," or, "Mr. Y will get you better fast, without pills; and if you do need pills, I can prescribe them, so you don't have to go to a shrink." These assertions may be essentially true, but they also suggest to the patient that the physician and the assistant or associate are offering not only the same result but the specialist's expertise in psychiatric diagnosis and treatment.

"The counseling [by the nonlicensed employee-counselor] shall be for those personal or family problems that the physician [himself or] herself would be competent to counsel directly had [he or] she not delegated such duties to the counselor."¹⁴ Similarly, such referral by a clinical psychologist should be for personal or family problems of a degree that does not warrant or require, by ordinary or prevailing standards of care within the field of clinical psychology, the full care of and treatment by a clinical psychologist or other appropriate licensed health professional.

Informed Consent

While not a statutory requirement, it is prudent that referral to the clinician's employee for counseling be defensively considered prescription of a procedure warranting the informed consent of the patient. The patient should be told the purpose and aim of the referral, that the particular counselor is not a licensed professional but is considered competent to provide assistance in obtaining a desired objective, that a licensed professional may alternatively be consulted for counseling or a second opinion. Full discussion should be provided so that the patient may make an informed decision. Caution would dictate that patients or clients should understand the extent of the physician's involvement in the treatment process, and comprehensive documentation of informed consents and supervisory or other contacts should be

maintained.

If the counselor is not an employee or otherwise associated except through the rental of space on the premises, it is appropriately defensive for the professional to disclose these circumstances, and to require the counselor to make this clear to clients derived from extrinsic sources. Neither the counselor's nor the physician's letterheads should bear the name of the other where they are independent practitioners. Whereas the patient should reassuringly be informed that the physician or psychologist bears continuing responsibility where this is so, the patient should be informed that the independent professional does not carry the burden of responsibility for treatment by the counselor who is a mere tenant offering independent services.¹⁵

Conclusion

Thus, whatever the motivation may be for provision of or affiliation with a nonlicensed counselor in the private practice of medicine, because the physician represents the "deeper pocket," the legal and, therefore, economic pitfalls run far and deep. On balance, it is easier to screen, more sound to rely upon, more respectful of patients' trust, and more clear to defend in court the conduct of a credentialed counselor. Through his or her employees and collegial relationships, the licensed professional places his or her liability and license on the line. If adequate supervision, direction, and control cannot be provided, a physician should not employ a nonlicensed counselor nor bill for his or her services. Since no procedure is totally secure, and licensed personnel may not be available, or the services of nonlicensed staff may be necessary, reference to these guidelines and consultation with counsel and/or insurer are advised.

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Old Age and New Policy

DANIEL CALLAHAN, PH.D.

IN the fall of 1987, the Reagan administration announced a 35.8% increase in the monthly Medicare Part B premium for 1988. This increase, from \$17.90 to \$22.80, was the largest annual rise in the history of the program. An increase of that size would have been expected to draw an instant protest. However, while there were groans from the elderly and others, it was as if a new realism had set in that protest would, in any case, do little good.

The simple truth is that health care for the elderly is expensive, that it will become even more so in the years ahead, and that no quick solution is at hand. Expenditures for the elderly under the Medicare program have increased at an inflationary rate of approximately 8% for the past few years; this is a rate twice the general pace of inflation. Despite almost two decades of trying, all efforts to control these costs have failed, and there is no reason to be hopeful about significant success in the future.

A recent study of the projected costs of the Medicare program, for example, presents figures of startling magnitude.¹ Under what the authors call "intermediate" projections, there will be deficits of \$27.3 billion by the year 2000, and \$117 billion by 2020. Those are the optimistic figures. Under more pessimistic but not improbable projections, the deficit will be \$62.5 billion by the year 2000 and \$210 billion by 2020. This means, the authors say, "that restoration of fiscal equilibrium for Medicare would eventually require that either its current projected tax burden be more than doubled or its currently projected expenditures more than halved."¹ These figures, moreover, are projections from the present Medicare programs; they do not include the many new proposals and pending bills for long-term and home care.

In light of these trends, I believe that nothing less than a full rethinking of the relationship between health care and old age will do. Costs will not be controlled or old age made meaningful unless we curb our insatiable appetite for a longer life regardless of the expense. There are

some fundamental but unavoidable choices in thinking about health care for the elderly. We can continue along the present path, tinkering endlessly with the present Medicare system and, as we do now, gradually increasing the premiums and out-of-pocket expenses for their recipients, or we can begin the bolder but now imperative task of asking what would be an acceptable and reasonable goal for health in old age. We need a more coherent and fair system and, to make that work, one that sets limits to care, particularly life-extending technological care.

But why won't tinkering work? We have allowed ourselves to be beguiled by dreams of greater efficiency. However, not one of the much-touted measures introduced to control costs during the past decade has had any noticeable impact. Consider the fate of the most prominent of such policies: the diagnosis related group system has reduced hospital inpatient costs only to drive up outpatient costs and the costs of short-term nursing care. The result has been a wash, with no significant overall reduction in cost increases. Increased competition that was meant to lower costs by giving consumers more choices, has, in fact, increased costs by stimulating a greater consumer desire for health care and competitive efforts to improve services. The health maintenance organization movement seems stalled for the time being, itself the victim of costs it cannot control. Efforts to use corporate economic muscle to extract bargains from providers have yet to succeed. In 1989, corporate health care costs are expected to increase anywhere from 20% to 70%.

The claim that billions of dollars can be saved if there were only greater rationality in the system—fewer unnecessary diagnostic procedures and useless, untested treatments—is perfectly plausible as an attractive theory, and "cutting the fat" is a wonderful slogan. However, possibility should not be confused with probability, and the failure after some 18 years of cost-containment programs should give pause to even the most congenitally optimistic person.²

As those efforts to cut the fat have failed in short-term care, thousands of elderly persons are forced to forego

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decent long-term or home care—options that are grossly underfunded by Medicaid. Many who do receive such care do so at the humiliating price of “spending down” their life savings and forcing themselves into the impoverishment that qualifies them for Medicaid assistance. We can, in short, neither control the costs of service that we do provide nor come up with the money for service that we do not provide.

Even in the face of these realities, however, there are many who would deny that there is a serious problem. We are an affluent country, it is said, and can afford to pay whatever good health care requires. In one sense, of course, we can: we can simply decide that health care expenditures for the elderly are more important than education, housing, general welfare, roads, and recreational facilities. But would it make sense to run a society that way, to let expenditures in one category—even a vital one—trump all other categories or to allow the needs of the elderly always take precedence over the needs of other age groups? Would that be fair? Would that be reasonable? I do not see how it could be, but that is what it would mean simply to give health care expenditures for the elderly a privileged position.

As an increasing number of public opinion surveys make clear, moreover, the public wants both *more* and *better* health care but is unwilling to pay significantly higher taxes to get it. As a recent study of public opinion by The Public Agenda Foundation concluded: “As concerned as they were about their vulnerability to the high cost of catastrophic insurance and long-term care...most of the participants...remained unwilling either to lower their own expectations about what the government should provide, or to pay what is necessary for even a modest level of government-provided coverage.... While there is strong support for more government involvement in this area, there is no corresponding inclination to pay for it.”³

However, even if we could or would spend much more on health care for the aged, *unlimited* disproportionate growth would not be tolerable, and the logic of modern high-technology health care is toward open-ended, unlimited expenditures. It envisions no stopping point at all. Right now, the very old do not receive a great deal of high-technology medicine. However, the trend is clearly in that direction, with a constant upward swing in the number of treatments and procedures originally developed for younger patients being applied to elderly patients. Pursuit of that course will not necessarily make old age more meaningful and satisfying—many of the elderly are already terrorized by the prospect that modern medicine will all too effectively keep them alive all too long—and it will surely divert money from the health and other needs of younger age groups.

An alternative would be to first recognize the failures of the present system. The present Medicare program creates a cruel imbalance between support for life-extending, high-technology medicine and that medical care necessary for a decent quality of life, most notably,

affordable long-term institutional care and decent home care. The success of medicine in saving and extending lives has meant a dramatic increase in chronic illness, especially for those over the age of 80 years. Our present system is utterly inept and insensitive in coping with that reality.

Over the short run, then—by which I mean the next ten to 20 years—we need to work toward righting the balance and shifting the emphasis of our entitlement programs. We should gradually move from a bias toward short-term, critical-care medicine for the elderly to the provision of well-funded, long-term and home care and all of those other needs of the elderly that improve the quality of their day-to-day life, though not necessarily extending that life. A longer average life span for the elderly will not necessarily be a better life. If a premature death has been avoided, there is after that no obvious correlation between length of life and human happiness. What the elderly want is physical and economic security, a sense of meaning and social significance, and the provision of care for their mundane needs. This phase of shifting emphasis will be one of increased costs, but the eventual goal will be to have an entitlement program and matching health care system that has a radically different set of priorities.

A second ingredient would be to accept the idea of limits on life-extending, high-technology care for the elderly. Those like myself who are not yet old, but who will be over the next two to three decades, must begin rethinking their own expectations about government-supported care. We cannot ultimately limit care at the frontier of old age on a case-by-case basis or by trying to work with the idea of individual need. Individual need in the case of the elderly will always be a matter of technological possibility and social expectation. People “need” what will stave off death and make them well; that is what we all desire. Despite its aura of objectivity, therefore, “need” is not a fixed, objective standard at all, nor can it ever be. It is culture and technology dependent and ever attached to subjective desires. For just those reasons, it cannot serve as an adequate standard for allocating resources. To say that we should use individual need as the standard is, in effect, to say that we should leave the large, social allocation questions to the individual physician at the bedside. However, for many years now, we have been hearing correctly, I believe, that rationing should not take place at the bedside.

In any case, unless we believe in an “invisible hand” of some kind, there is no reason to believe that what is right for each individual will be exactly what we can afford or what makes sense for the society as a whole. These are the pitfalls of rationing on a case-by-case basis. We need a more fair and more uniform standard to make these decisions, and I propose that a flat age limitation on the most expensive forms of life-extending care would meet that standard.

How would we select an age? I think we now have

cultural traditions and common expectations that can be built upon to fashion such a standard. We can think in terms of a "natural life span," not natural biologically, but natural in the sense of our common biographies. By their late 70s or early 80s, most people have had a chance to do most of what a human life offers—to love, to raise a family, to travel, to think, to read, to enjoy nature, and to make sense of their lives and destinies. It is not that a longer life would not afford more possibilities; of course, it would. However, it is not reasonable to expect that a public entitlement program should be tailored to our individual needs and desires. I might well want to live to be 100 or 105 years old, and I might well need an artificial heart to help me do so. Yet it would not be reasonable, when faced with other social needs, for my neighbor to be taxed to pay for my achievement of that goal. I can only ask of him that he help me to avoid a premature death, to live a reasonably long life, and to make my last years as comfortable as possible. That goal is compatible with setting a specific age limit, one that we could, as a society, collectively decide upon and use as a limitation on Medicare coverage (though never to limit the relief of pain and suffering). It would not be wholly fair, but then there are no ways of setting limits that can be wholly fair. In any case, no plausible alternatives have ever been proposed.

But would it not be "ageist," as some advocates of the elderly claim, to use age as a standard to limit life-extending care? Not at all, if it was done in the name of

providing a higher quality of life for the elderly by beginning a transfer of emphasis from short-term-care medicine to other forms of care, notably, long-term and home care. What is required is a better balance between the kinds of care the elderly need. A proper balance—to be affordable—would require limits on the life-extending care, but the result would be a more full, more coherent care program. This approach would not be an assault on the dignity of the elderly if viewed with respect for the needs of everyone and with a more unified vision of the life cycle. At present, the elderly have the privilege of the only entitlement program that is not based on need. To suggest that what is, in the first place, a very special program and admit some ultimate limit is not to deprive and denigrate the elderly: it is only to recognize that we live in a finite world.

We do need a new vision of health care for the elderly. A medical care system that would give each of us an adequate but not indefinitely long lifetime, and that accepted death in old age, would be one both more humane for the elderly and financially sensible for everyone else. Medicine cannot conquer death or old age, but it can bankrupt us trying to do so.

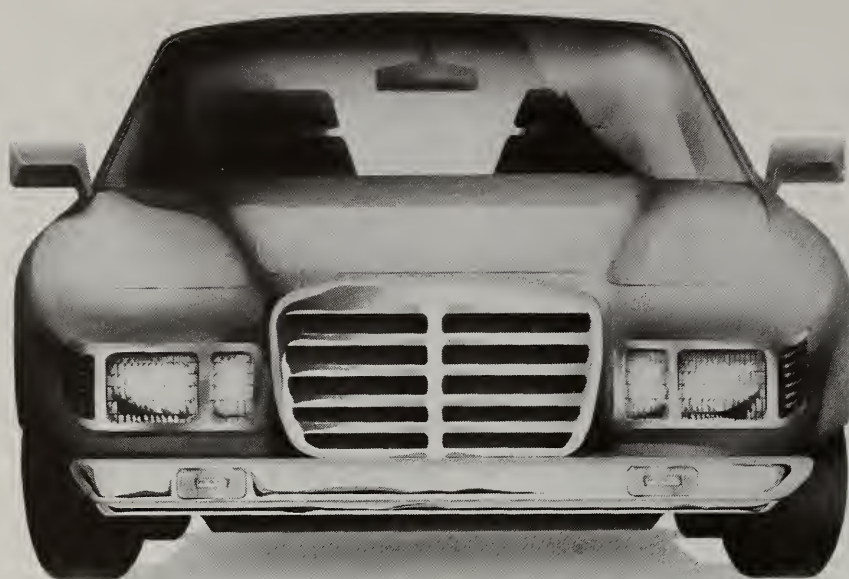
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CSMS Keeps Courtesy Card in Effect for Services

The Connecticut State Medical Society is aware that the deadline for use of the CSMS Medical Courtesy Card passed on December 31, 1988. By this date, it was hoped that all holders of the Courtesy Card would have applied for and received a State of Connecticut Medicare Assistance Program (ConnMAP) Card in order to continue to receive the benefits of the assignment program. However, because many seniors have not had their Courtesy Cards replaced, CSMS is urging member physicians throughout the state to continue to honor the Courtesy Card for seniors who have not yet received their new state cards and to advise their senior patients who have not yet applied for the ConnMAP card to contact the State Department on Aging immediately.

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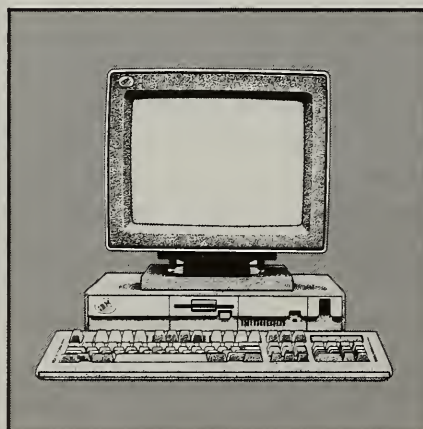
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Options to Control the Rising Health Care Costs of Older Americans

EDWARD L. SCHNEIDER, M.D.

WILL our economy be able to withstand the increasing health care costs of older Americans? These per capita costs increase as a function of the age of our adult population and escalate rapidly in the last years of life. For example, the average Medicare reimbursement per person for those aged 65 to 66 years is \$1239 compared with an average cost of \$2583 for those aged 85 years and older.¹ The future growth of the population of those aged 85 years and over, a group frequently referred to as the "oldest old," will have a substantial impact on future health care costs. This age group is currently the fastest growing age cohort in the United States,² and it is projected to grow from 2.5 million persons in 1980 to as high as 24 million persons by the year 2040.³ The current health care needs of this group are impressive. While only 1% of those aged 65 to 74 years reside in nursing homes, as many as 25% of women and 15% of men aged 85 years and older are currently nursing home residents.⁴ Therefore, if the level of morbidity remains the same in this group (and there is no compelling evidence to indicate that it will change in the near future^{5,6}), the costs for short- as well as long-term health care for this age group alone may increase tenfold.

Several measures have been proposed to reduce the projected growth of health care costs for older Americans. One approach is to reduce the per capita costs of care. Callahan,⁷ in a companion article in this issue of *The Journal*, outlines the failures of past cost-containment strategies. He is appropriately skeptical about future strategies oriented toward reducing the projected increasing costs of health care. Moreover, even if health care costs for older Americans could be reduced by 50%, which is a reduction that would be considered a great success by most, the projected 500% to 1000% increase in the number of those aged 85 years and older would more

than offset these gains.

Another response to the increasing costs of health care for older Americans is a proposal that age limits be set for the allocation of government-supported health benefits.^{7,8} I would like to argue that age is neither a valid nor defensible criterion for rationing health care. In addition, I would like to offer an alternative course of action that I believe will provide a more satisfactory outcome—investment in research targeted toward preventing those diseases that produce the greatest need for long-term care in our aging population.

Without defining a specific age, Callahan proposes to ration life-extending high-technology health care to those who have completed their "natural life span." This term assumes that policymakers could reach a consensus on a specific age when people have lived a full life. It may also assume that individuals complete a portion of life full of accomplishment and free of disability and then move to a period of infirmity and diminished productivity to await death. While an abrupt transition from health to disability may occur in some situations, such as fractures of the neck of the femur, in the vast majority of aging Americans this transition is gradual. Furthermore, many individuals continue to make important contributions in their last years of life.

One major problem with rationing any commodity, including health care, is that it often results in limited resources for the poor. Under the National Health Service in Great Britain, many aspects of health care are rationed. While age is not overtly mentioned as a criterion, the more expensive health care procedures, such as dialysis and coronary bypass surgery, are rationed by age and usually limited after age 55.⁹ Affluent, older Britons have little difficulty obtaining these procedures at private clinics. In fact, private health care is booming in Great Britain.

Callahan's proposed rationing of health care for older Americans includes withholding Medicare reimbursement for all technology, including antibiotics, and limits care to providing relief from pain and suffering.⁸ Cer-

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tainly, physicians and relatives of affected victims need to consider the ethics of administering antibiotics to victims of Alzheimer's disease whose quality of life is distressingly compromised. At the same time, I would vigorously oppose any proposal to eliminate Medicare entitlement for antibiotic therapy for an otherwise healthy 85-year-old individual with acute pneumococcal pneumonia. Blanket restrictions on entitlements based on age are irresponsible and would be difficult to administer. Refusing to permit hip replacements would not only lead to disability and dependency but would lead to increased costs for long-term care. Furthermore, most of the costs for the major diseases and disorders that disable older Americans—Alzheimer's disease, osteoarthritis, and Parkinson's disease—are not currently covered by Medicare, which is oriented toward short-term medical care.

My biggest concern about health care rationing is the use of age as a criterion for withholding care. This is a step backward that removes families, affected individuals, and their physicians from the decision-making process. Any decision to withhold care should be made based on other criteria such as the prognosis of the patient and the desires of the patient and family members. When age is employed as a criterion for decision making, it infers that older individuals make up a homogeneous group. Every health practitioner is aware of the heterogeneity in the processes of aging. Studies of metabolic processes reveal an enormous heterogeneity of response to aging, with some individuals having significant declines in functions with aging while others have minimal impairment.¹⁰

The principal rationale employed for the rationing of health care based on age is to preserve resources for future generations. This issue of intergenerational equity has been raised by others to justify the need to limit resources for our older population to preserve them for younger age groups.¹¹ However, there are several weaknesses in this reasoning. First, it assumes that our resources for medical care are fixed at some level. I find it hard to justify continuing subsidies for tobacco and sugar while cutting health benefits for older Americans. Second, there is no guarantee that the money saved would be reallocated to children and young adults. Finally, we are not taking away resources from one distinct group and giving them to another. Aging is a continuum and if death does not intercede prematurely, the youth of today will be the recipients of medical care resources in their later years.

Future health care costs for the elderly are dependent on the number of individuals achieving these later years of life, the age-related costs of health care, and the health status of individuals at different ages. The numbers of persons reaching older ages will increase as life expectancy increases and as the "baby boomers" approach the last years of life. Even if the average cost of care were to be decreased, it is unlikely that it would diminish enough to offset the enormous numbers of persons who will

reach the oldest age groups.

I would like to offer a more optimistic and, I believe, rational approach to curb our burgeoning health care costs for older Americans, one that offers ample opportunity to improve the health of older Americans. This is to increase biomedical research into the disorders that afflict older persons. The list of diseases and disorders that require increased attention includes Alzheimer's disease, Parkinson's disease, osteoarthritis, and osteoporosis. The incidence of each of these disorders increases exponentially with aging.¹² Each produces years of disability that require long-term health care. For example, a recent survey of the prevalence of Alzheimer's disease among older Americans dwelling in the community revealed a prevalence of 4% for those aged 65 to 74 years and 48% for those aged 85 years and older.¹³ Surveys of nursing homes indicate that approximately half of current nursing home residents have dementia, with Alzheimer's disease as the most prevalent cause.⁴ In 1983, the cost for care of the 2 to 3 million patients with Alzheimer's disease was estimated to be \$38 billion.¹⁴ As millions of Americans surpass age 85, the number of victims of Alzheimer's disease will increase dramatically, resulting in enormous costs to our nation.

Despite the very large current and projected costs for these diseases, significant federal research support has only occurred in the last few years. In contrast to the substantial cost of services for victims of Alzheimer's disease, research funding amounted to 0.1% to 0.2% of the cost of services.¹⁵

Recognizing the enormous potential social and economic consequences of the acquired immunodeficiency syndrome, Congress has significantly increased its appropriations for research on this condition. The increased research support has resulted in an unsurpassed acceleration of scientific research devoted to acquired immunodeficiency syndrome during the last few years. The diseases and disorders associated with aging need a comparable response. Successful prevention and/or cure of these conditions would result in significant reductions in projected health care costs for older Americans.

It can be argued that the success of biomedical research has resulted in the increased life expectancy that is threatening our health care system and that further research might produce additional and new burdens. During the first half of this century, most applied biomedical research was focused on acute diseases. As a result, the three leading causes of death at the turn of this century, all infectious diseases, no longer produce significant mortality in the United States. Today, the three top causes of death are chronic conditions: heart disease, cancer, and stroke. We are now witnessing a substantial decline in mortality from myocardial infarction and stroke. As a result, more individuals are reaching the eighth and ninth decades of life, where diseases such as Alzheimer's disease, Parkinson's disease, and osteoarthritis

tis take their toll. In contrast to acute diseases, these disorders require abundant long-term health care services. It is unlikely that the conquest of diseases such as Alzheimer's disease could result in the emergence of more costly conditions. Instead, it may be possible that the conquest of these diseases and disorders of aging could lead to the compression of the needs for long-term care into a few short months or years. Then, the human life span might approach Oliver Wendall Holmes' "one-hoss shay," a shay built so well that after long use, "it went to pieces all at once."¹⁶

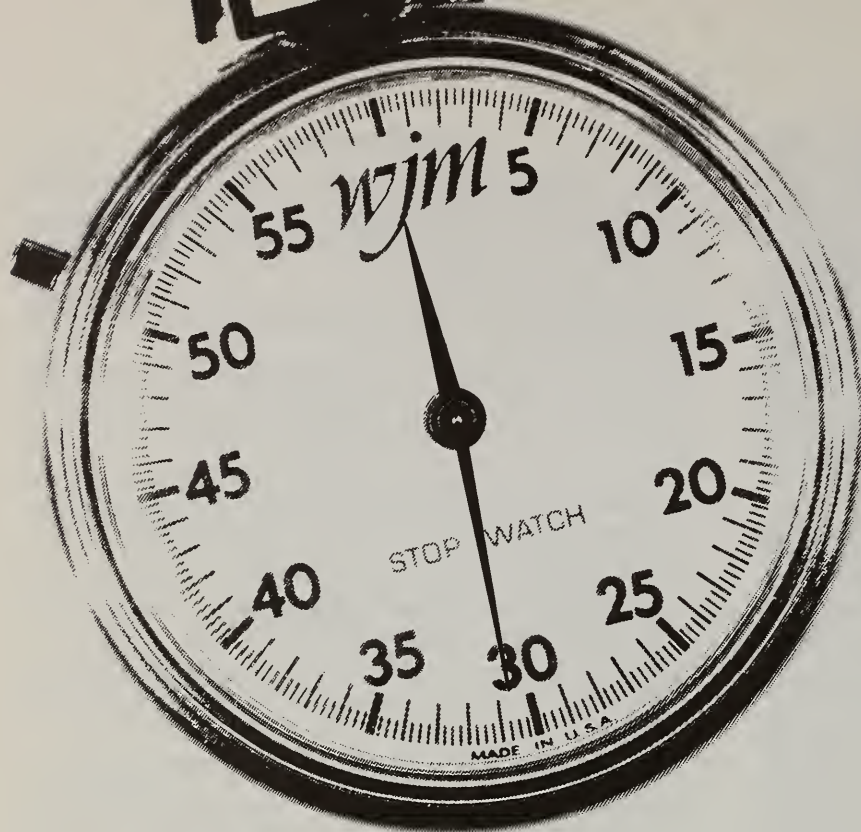
To put into perspective the need for concentrating on preventive and therapeutic approaches, let's examine our approach to other diseases that have required significant costs for long-term care. If 40 years ago, we had decided to ration care for tuberculosis, instead of providing support for the development of new therapies, the prevalence and cost of this disorder would be several magnitudes greater than current costs. If we had decided to limit life-extending technology for polio victims instead of supporting the development of vaccines, we might be facing enormous costs for long-term care of polio victims. Therefore, it is imperative that before we ration health care, we provide the necessary resources to develop effective preventive and therapeutic approaches to those diseases and disorders that disable our older population. We run the risk of committing an unnecessary and probably fatal political and ethical error unless we make this relatively inexpensive research effort. If we invest in research on the diseases of aging, we may be able to provide healthier, more productive, and fruitful years for ourselves and for future generations.

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I would like to thank T. Franklin Williams, MD, Jacob Brody, MD, Christine Cassel, MD, Carrol L. Estes, PhD, Hilary Siebens, MD, and Leah Buturain Schneider, MS, for their suggestions and Lorren Luchi and Lori Rosenquist, MS, for their assistance.

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TO ALL CONNECTICUT PHYSICIANS:

Procedures for Screening Nursing Home Applicants

LINDA J. SCHOFIELD

THIS memorandum summarizes briefly recent federal statutory requirements governing the admission of patients to nursing homes. The State of Connecticut Department of Income Maintenance is accountable for compliance with this new Act and is seeking the assistance and cooperation of the medical community, as well as nursing homes and hospitals, in assuring efficient and appropriate implementation. Procedures for completing and seeking reimbursement for physician services to nursing home applicants are described below.

The federal "Nursing Home Reform" provisions of the Omnibus Budget Reconciliation Act of 1987 mandate that no person (regardless of payment source) be admitted to a nursing home after 1 January 1989, unless that person has been screened to determine whether he or she requires active treatment for mental illness or mental retardation. For the vast majority of people, this will simply require the completion of an identification form which lists key criteria indicating a possible condition of mental illness or mental retardation. This identification form will be completed by hospitals for their patients, and by nursing homes for applicants from the community. If the nursing home does not have sufficient information about the prospective resident to complete the identification form, the identification form will be sent to the applicant's physician along with a self-addressed stamped envelope to return the form to the Department.

We ask that you *complete the identification form within two days of receipt.*

If the identification form indicates that the person does not have a positive indication as defined by the criteria, or if the person is exempt as outlined on the identification screen, no further reviews are necessary, and all current state preadmission screening and admission procedures apply. If, however, the identification form indicates the need for further evaluation, a more

extensive assessment is required to determine definitely whether the person needs active treatment for mental illness or mental retardation.

The first step in this assessment is the completion of a Medical Supplement Form by a physician or another health professional familiar with the patient's medical condition and history. For community-residing patients, the nursing home will send the physician (with the identification form—unless it has already been completed) a Medical Supplement form. Please complete and sign the *medical supplement form only if the identification form indicates that the patient requires further evaluation.*

If the individual has not had a physical examination within one year, then a physical must be performed prior to completing the Medical Supplement Form. *We ask that you return the appropriate completed forms to the Department within ten working days of receipt in order to assure timely service to the patient.*

Additional screening forms will usually be completed by hospital staff or the Department Preadmission Screening field office staff. However, physicians may occasionally be asked to complete these forms for their hospitalized patients. One of these forms is the Uniform Health Screen, which is currently being used in the Preadmission Screening and Community-Based Services Program to collect data on the person's functional and psychosocial status. The other forms have been designated by the Department of Mental Health to collect data and service information related to a possible condition of mental illness. These are the Psychotic Inpatient Profile Form ("PIP") and the profile of services.

The federal law specifically requires that the preadmission screening process must be completed *before a patient can be admitted to the nursing home.* Failure to comply could result in the loss of federal Medicaid funding and decertification of the long-term care facility. The law provides for no exceptions to this process, although the state has authorized emergency admissions for persons whose health and safety are endangered.

LINDA J. SCHOFIELD, Director, Medical Care Administration, Department of Income Maintenance, State of Connecticut, Hartford, CT 06106.

In order to assure that this screening process does not delay hospital discharges or nursing home admissions, the state has instructed providers to identify potential nursing home admissions and initiate the screening process as early as possible. Hospitals will be identifying *potential* nursing home discharges within three days of admission and completing all of the appropriate forms. Nursing homes are required to start the screening process on applicants residing in the community when it is projected that a bed will be available in approximately 60 days.

The Department will pay physicians \$11.05 for completion of a Medical Supplement form, \$30.42 for performing a physical if one is necessary, and \$55.00 for completion of (on a hospitalized patient) a required evaluation of mental illness (psychotic inpatient profile form). These payments are available for both Medicaid and non-Medicaid nursing home applicants. Federal guidelines prohibit payment for completion of the iden-

tification form. Details on the payment procedures are still being finalized; this information will be conveyed to you as soon as possible. But, in the meanwhile, the Department will keep track of all services provided and will assist you with appropriate billing, if required, in the future. Please note, however, that the Department will not pay for procedures that were not required to comply with the preadmission screening law.

If you believe that the response to questions on the identification form "falsely" indicates the need for further evaluation, please call Ginnie Getchell at 566-6646 to discuss the case. You should also contact Ginnie if you have other questions about the screening process.

The Department is actively working with providers to make this mandatory process as efficient as possible. We ask for your patience and cooperation, and welcome any suggestions as we work to improve this system. Thank you for working with us to serve our patients.

Mortality Trends — United States, 1986-1988

The leading causes of death in the United States are monitored by mortality data from the National Vital Statistics System (see page 118). In 1986, 1987, and the 12-month period October 1, 1987, to September 30, 1988, death rates decreased for some of the leading causes of death, including two of the three leading causes: heart disease and stroke (Table 1). However, the rate for the second leading cause, cancer.

TABLE 1. Annual death rates per 100,000 population for the 10 leading causes of death — United States, 1986, 1987, and October 1, 1987—September 30, 1988*

Rank order	Cause of death (ICD-9)	Rate		
		Final [§] 1986	Provisional [†]	
			1987	10/1/87- 9/30/88
	ALL CAUSES	873.2	874.0	885.8
1	Diseases of heart (390-398,402,404-429)	317.5	313.4	314.2
2	Malignant neoplasms, including neoplasms of lymphatic and hematopoietic tissues (140-208)	194.7	196.1	197.5
3	Cerebrovascular diseases (430-438)	62.1	61.3	61.3
4	Accidents and adverse effects (E800-E949)	39.5	39.0	38.7
	Motor vehicle accidents (E810-E825)	19.9	20.1	19.7
	All other accidents and adverse effects (E800-E807, E826-E949)	19.7	18.9	19.0
5	Chronic obstructive pulmonary diseases and allied conditions (490-496)	31.8	32.2	33.2
6	Pneumonia and influenza (480-487)	29.0	28.8	31.1
7	Diabetes mellitus (250)	15.4	15.6	16.1
8	Suicide (E950-E959)	12.8	12.7	11.7
9	Chronic liver disease and cirrhosis (571)	10.9	10.7	10.9
10	Atherosclerosis (440)	9.4	9.5	9.6

* References 1-3.
† Based on a 10% sample.
§ Based on all deaths.

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—*Morbidity and Mortality Weekly Report*, March 3, 1989.

Hospital Spending in the United States and Canada: A Comparison

JOSEPH P. NEWHOUSE, GEOFFREY ANDERSON, AND LESLIE L. ROOS

Prologue: *The rate at which Canada's citizens are hospitalized is high (1,242 days per 1,000 residents) and the lengths-of-stay for all levels of care in private voluntary hospitals long (11.5 days). Canada's hospitals negotiate their budgets every year with, for all practical purposes, the lone payer of care—the provincial health insurance plan where they operate. In this paper, Joseph Newhouse, Geoffrey Anderson, and Leslie Roos explore the question: What accounts for the substantial differences in hospital spending between such institutions in Canada and the United States? Comparisons both between and within countries are complicated by the difficulty of defining similar hospitals and similar patient populations. Nevertheless, the question they address is compelling and warrants examination. Newhouse, an economist, is the John D. and Catherine T. MacArthur Professor of health policy and management at Harvard University. He holds a joint appointment at the Harvard Schools of Government, Medicine, and Public Health. Newhouse is also codirector of the Harvard-RAND-UCLA consortium, which provides policy analysis on selected health issues to the Health Care Financing Administration. Before joining the Harvard faculty this summer to build a strong doctoral program in health policy, Newhouse directed The RAND Corporation's Economics Department. He was the principal investigator of RAND's fifteen-year, \$82 million, federally funded health insurance study, the largest randomized trial of health care financing ever undertaken. Anderson, a physician who also holds a doctorate in health policy from the RAND graduate program, is on the faculty of the University of British Columbia. Roos, who received his doctorate in political science from the Massachusetts Institute of Technology, is a member of the faculty of management at the University of Manitoba. Roos has built a distinguished career in health services research, in part by mining a rich claims database maintained by Manitoba's provincial health insurance plan.*

NUMEROUS health policy analysts on both sides of the border have discussed the Canadian method of financing medical care as a possible model for the United States.¹ Canada not only has achieved universal coverage but spends substantially less per capita on health than the United States. Those favoring the Canadian model have tended to assume that the savings in cost come with minimal or no effect on the quality of care or health outcomes. On the contrary, because of universal coverage, health outcomes averaged over the Canadian population as a whole may even exceed those in the United States. However, the U.S. debate over whether the Canadian system is superior has paid less attention to health outcomes than to differences in cost and coverage levels. In Canada, by contrast, there is no serious advocate of the U.S. system.

In this article, we do not examine differences between the two countries in health outcomes, but we do examine the differences in the use of acute care hospitals—the largest single component of health care expenditures in both countries. We compare the countries in terms of three measures of hospital utilization: (1) admissions, (2) length-of-stay, and (3) case-mix, measured using the weights attached to the diagnosis-related groups (DRGs) of the U.S. Medicare program. We limit the analysis to the care provided to individuals age sixty-five and older because they receive universal public insurance in both countries.² Thus we can attribute differences in use to factors other than differences in insurance coverage and can compute rates of use for defined populations. While our analysis does not compare the ultimate effects of differences in health care expenditures between the two countries, it does provide a first step toward a better understanding of the factors that drive those differences.

Hospital Use In The United States And Canada

We compare utilization in two Canadian provinces with both the United States as a whole and selected states geographically close to the two provinces. We chose the two provinces because of data availability. However, they contain 40 percent of the Canadian population; also, results for the two provinces are similar, suggesting

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that our conclusions may hold for a comparison of all of Canada with the United States.

Data sources and numbers. For the United States, our data come from a 20 percent sample of all Medicare hospital claims in calendar year 1981 and fiscal years 1984 and 1985. From this file we deleted claims from the four states that at that time had waivers from the prospective payment system (PPS)—Maryland, Massachusetts, New Jersey, and New York. Thus, references to the entire United States mean only forty-six states. We also deleted claims from Puerto Rico and the Virgin Islands, although including them would have negligible effects because they are so small. We also deleted claims for those under age sixty-five.

For Canada, the data come from a 100 percent sample of claims from Ontario and Manitoba. Although we compare both provinces with the entire United States, we also compare Ontario with Michigan and Ohio, and Manitoba with North Dakota and Montana. The samples from each of the two-state areas are about half as large as the comparable provinces.

Type of provider and case-mix. The goal of our analysis was to compare the use of acute care hospital services in the two countries. However, differences in the definitions of institutions and units exist. To make our comparisons as similar as possible, we excluded cases in rehabilitation and long-term care hospitals and units. We used the following methods to define use of acute care beds.

In Ontario, each discharge abstract contains a variable that identifies the institution from which the individual was discharged. Each institution is assigned a unique identifier. Long-term care and rehabilitation units within acute care hospitals are assigned identifiers that are distinct from the number assigned to the acute care section of the hospital. A transfer from an acute care section to a rehabilitation or long-term care section of the same institution produces a discharge abstract. A discharge was included in the analysis only if it was from an identified acute care institution. Discharges from acute care psychiatric units were included.

In Manitoba, each discharge abstract contains a service code indicating the type of care received by the patient during the admission. Patients receiving personal care, physical medicine and rehabilitation, geriatrics, and extended treatment were excluded from the analysis. Patients receiving psychiatric or psychogeriatric care were included.

In the United States, certain hospitals—rehabilitation, chronic or long-term, psychiatric, and children's—were exempt from PPS, which began in October 1983. Unfortunately, we cannot identify these exempt hospitals in 1981. We have therefore estimated 1981 admission and case-mix figures using the relationship between acute care hospitals (and psychiatric hospitals) and all hospitals in 1984 and 1985. Specifically, to estimate a figure for

admissions and the case-mix index for 1981, we used the admission (case-mix) figure for all hospitals for 1981 and multiplied it by the ratio of admissions (case-mix) in all hospitals other than long-term and rehabilitative to admissions (case-mix) in all hospitals. This ratio was available for both 1984 and 1985; we averaged the two values.

Only around 5 percent of all admissions occurred in rehabilitative and long-term care hospitals and units in both 1984 and 1985, and, if anything, the value was probably lower in 1981 because of fewer such units. Our method for estimating a 1981 rate therefore effectively decreased the admission rate to all hospitals (including rehabilitative and long-term) in 1981 by about 5 percent. The resulting 1981 admission rate for the United States may be slightly too low, but any error is almost certainly not serious enough to affect the comparisons with Canada.

The value for the case-mix index is about 1 percent higher in both 1984 and 1985 if cases in rehabilitation and long-term hospitals and units are excluded. Hence, our methods led us to increase the case-mix index for all hospitals in 1981 by about 1 percent. That adjustment also does not affect any of our comparisons.

Length-of-stay. Unlike admissions and the case-mix index, the 1981 length-of-stay values are sensitive to the adjustment process, because of the long lengths-of-stay in rehabilitation and long-term care hospitals and units (mean values in the United States of fifty days in 1984 and thirty-five days in 1985). To reduce the sensitivity of our length-of-stay comparisons to errors in classification of cases, we began by computing not only the usual mean but also a trimmed mean by setting all stays of over sixty days equal to sixty days. This reduces the influence of very long-stay cases. However, when we then adjusted the 1981 U.S. values in the same way that we adjusted admissions and case-mix, we obtained the anomalous result that the adjusted trimmed length-of-stay exceeded the adjusted untrimmed length-of-stay. Hence, we have followed the simple step of reporting the length-of-stay values for all U.S. hospitals for 1981 (both untrimmed and trimmed). Although this will overestimate length-of-stay in hospitals other than rehabilitation and long-term, the values are still well below the Canadian values, so that our qualitative conclusions are unaffected. In the U.S. data, we have excluded discharges from skilled nursing facilities.

Population data. U.S. enrollee data come from the Health Care Financing Administration (HCFA). These data are for 1984 and come from aggregating enrollees by zip code. To project the number of enrollees for 1981 and 1985, the total number of Part A enrollees over age sixty-five in 1981, 1984, and 1985 in the entire country was used.³ The number of enrollees in each of the two subregions analyzed in 1981 and 1985 was assumed to change proportionally the same as the national number (0.9439 for 1981 and 1.0211 for 1985, both relative to

1984). In Canada, federal support for the provincially administered health care systems is contingent upon universal coverage of the population. Therefore, census data were used to identify the eligible populations in Ontario and Manitoba.

We have not age- and sex-adjusted our figures because the age-sex distributions are virtually identical. Using five-year age groups for each sex (through age eighty-five), the percentage of the population in each group in North Dakota and Montana is always within one percentage point of the group in Manitoba; similarly, the percentage for Michigan and Ohio is almost always within one percentage point of the group in Ontario (one case differed by 1.3 points). We cannot compare costs or charges at the case level directly because Canada does not associate costs or charges with a particular case in its global budgeting method.

Results Of The Comparison

As is commonly known, real personal health expenditure per person is substantially higher in the United States than in Canada; we estimate that the United States spent about 50 percent more per person throughout the first part of the 1980s (Exhibit 1). Similar percentage differentials also applied to hospital services. Hospital expenditure per capita in Manitoba is identical to that in all of Canada.

Exhibit 1
Health Expenditure Per Capita In The U.S. And Canada, 1981-1985, 1985 U.S. Dollars*

Year	United States		Canada		Manitoba
	Personal health expenditure per capita	Hospital expenditure per capita	Personal health expenditure per capita	Hospital expenditure per capita	Hospital expenditure per capita
1981	\$1,260	\$590	\$ 800	\$380	\$380
1984	1,440	670	1,010	470	470
1985	1,500	680	1,010	460	460

Sources: Data for United States 1981, 1984, K. R. Levin et al., "National Health Expenditures, 1984," *Health Care Financing Review* (Fall 1985); for 1985, D. Waldo et al., "National Health Expenditures, 1985," *Health Care Financing Review* (Fall 1986). Data for Canada, *National Health Expenditures in Canada, 1975-1985; National Health and Welfare, 1987; Quarterly Economic Review*, Annual Reference Tables (Department of Finance, Canada, June 1987); Manitoba Health Services Commission, Annual Reports. Converted to U.S. dollars at exchange rates of 1.199 for 1981, 1.295 for 1984, and 1.366 for 1985.
*Uses United States gross national product (GNP) consumption deflator.

To examine in more detail what might account for these differences in the level of hospital expenditure, we examined admission rates and lengths-of-stay between 1981 and 1985 (Exhibits 2 and 3). Admission rates were comparable between Michigan/Ohio and Ontario in 1981 and 1984, and were lower in Michigan in 1985. Although admission rates in Montana/North Dakota fell 15 percent from 1984 to 1985, they remained about 10 percent above those in Manitoba and well above those for the United States. On the whole, by 1985, admission rates in the two countries seem approximately the same. In contrast, length-of-stay differs markedly between the

Exhibit 2
Hospital Admission Rates For People Over Age Sixty-Five, Selected States And Provinces

Year	Ontario	Michigan/Ohio	Manitoba	North Dakota/Montana	All United States*
1981	.33	.33 ^b	.32	.41 ^b	.34 ^b
1984	.35	.36	.32	.44	.37
1985	.35	.32	.34	.38	.33

*Excludes waiver states of Maryland, Massachusetts, New Jersey, and New York.
^bEstimated; see text.

two countries. Length-of-stay in Manitoba was approximately double the length-of-stay in Montana/North Dakota, while length-of-stay in Ontario was notably longer than in Michigan/Ohio, especially by 1985. North Dakota/Montana had somewhat shorter stays than the U.S. average, and Michigan/Ohio had somewhat longer stays.

Exhibit 3
Length-Of-Stay For People Over Age Sixty-Five, Selected States And Provinces, In Days

Year	Ontario	Michigan/Ohio	Manitoba	North Dakota/Montana	All United States*
1981	14.43	11.11 ^b	15.88	8.35 ^b	9.90 ^b
1984	14.48	9.40	15.38	7.64	8.66
1985	14.25	8.60	15.77	7.16	8.07

*Excludes waiver states of Maryland, Massachusetts, New Jersey, and New York.
^bValue is overestimated because it includes stays at rehabilitation and long-term care hospitals and units; see text.

To determine how length-of-stay might be affected by very long-stay patients, we recomputed the mean length-of-stay by trimming stays at sixty days (that is, patients with stays longer than sixty days were set equal to sixty days). The results are shown in Exhibit 4. Stays in Manitoba are particularly affected, falling by three to

Exhibit 4
Length-Of-Stay For People Over Age Sixty-Five, Selected States And Provinces, Stays Trimmed At Sixty Days

Year	Ontario	Michigan/Ohio	Manitoba	North Dakota/Montana	All United States*
1981	13.27	10.98 ^b	11.07	8.23 ^b	9.75 ^b
1984	13.43	9.25	12.29	7.41	8.48
1985	13.32	8.48	12.16	6.77	7.96

*Excludes waiver states of Maryland, Massachusetts, New Jersey, and New York.
^bValue for all hospitals; see text.

four days. Values for the United States are not much changed. Nonetheless, even after reducing the effect on the mean of these very long-stay patients, there remain substantial differences between the countries in mean length-of-stay.

Results for the case-mix index are somewhat difficult to interpret because of the rapid increase in the U.S. index, much of which has been attributed to better coding procedures (Exhibit 5).⁴ By contrast, the values for Canada have increased at a rate of half a percent to a percent a year, which is similar to the pre-PPS trend of a half percent a year that Grace Carter and Paul Ginsburg estimated for the United States.⁵

Exhibit 5
Case-Mix Index For People Over Age Sixty-Five, Selected States And Provinces

Year	Ontario	Michigan/Ohio	Manitoba	North Dakota/Montana	All United States*
1981	1.10	1.08 ^b	1.07	0.96 ^b	1.01 ^b
1984	1.11	1.13	1.08	1.10	1.12
1985	1.12	1.19	1.09	1.20	1.19

*Excludes waiver states of Maryland, Massachusetts, New Jersey, and New York.
^bEstimated; see text.

What Accounts For The Difference?

In the early 1980s, the United States spent nearly 50 percent more per person on hospital services than Canada; the important question is what, if anything, the United States bought for that additional expenditure. To shed light on that question, we have decomposed hospital spending in two provinces and compared the anatomy of that spending with two comparable areas in the

United States and the United States as a whole.

Overall, our findings, which apply only to the elderly, somewhat deepen the puzzle of what the United States might be buying. By 1985, admission rates were roughly comparable in the two countries, being somewhat higher in North Dakota and Montana than in Manitoba, but somewhat lower in Michigan and Ohio than in Ontario. The U.S. admission rate was marginally below that of the two provinces. Hence, the differences in spending between the two countries cannot be attributed to a higher rate of hospital admissions in the United States.

In each of the three years we examined, lengths-of-stay were markedly longer in Canada. The considerable fall in length-of-stay in the United States was not matched in Canada. By 1985, lengths-of-stay in Ontario were more than two-thirds again as long as in Michigan and Ohio, and in Manitoba were more than double the lengths-of-stay in North Dakota and Montana. Because admission rates were roughly similar (in 1985), the number of patient days per person over age sixty-five in the United States are only 50 to 60 percent of the corresponding number in Canada. It follows from the values in Exhibit 1 that spending per patient day is perhaps three times as great in the United States as in Canada.

Case-mix. To understand why the United States might be spending half again as much per case and three times as much per day, we examined the case-mix index for the two countries. Comparison between the two countries is complicated by the rapid rate of increase in the U.S. index that can be attributed to PPS. Coding now affects the hospital's reimbursement; this has resulted in both a substantial increase in the accuracy of the coding and an incentive to code cases in higher-weighted DRGs. Neither of these effects was present in Canada.

If we judge the comparability of case-mix using data from 1981, a time when coding incentives in the two countries were more nearly similar, the case-mix index is higher in Canada; this is especially true of the comparison between Manitoba and North Dakota/Montana. In 1984 the two countries were roughly comparable, although by 1985 the United States had a somewhat higher case-mix index. If one could adjust for upcoding, however, it is likely that the 1985 U.S. value would be equal to or below the Canadian.⁶ The similarity of the annual change in case-mix in Canada with the annual U.S. change prior to PPS strongly suggests that most of the change in the United States was not true change. Even if the 1985 difference between the United States and Canada is true (which we think is unlikely), case-mix, as measured by DRGs, can at best account for only a small portion of spending differences.

Thus, the difference in hospital spending between the two countries, which may account for around 40 percent of the difference in total expenditure between the two countries, must be accounted for primarily by differences in the cost of a "case-mix index unit" per beneficiary.

With admissions and the case-mix index in the two countries at approximately the same level, the cost of a case-mix unit in the United States was approximately 50 percent higher than in Canada. What might account for such a difference? The Canadian method of global budgeting, of course, makes it easier to control costs, and some discussions appear to assume that the additional American costs are pure inefficiency. However, other factors ought to be considered.

Severity of illness. Differences in severity or complexity within DRGs could be such that American patients are sicker. There is no reason, however, to think that this is the case; indeed, the similar admission rates and longer lengths-of-stay in Canada, if anything, point in the other direction. Lack of insurance coverage, which could lead to increased severity of illness in some under age sixty-five admitted to a U.S. hospital, should not play an important role in the Medicare population.

Volume of services. American patients could have more done to or for them when in the hospital. Not only could there be more tests and other ancillary procedures, but staffing ratios could be higher. Indeed, staffing ratios per patient day in the United States appear to be almost double those in Ontario. There were 3.47 employees per adjusted census in nonfederal short-term general and other special hospitals in the United States in 1981, and 1.87 per inpatient day in 1980-1981 in Ontario.⁷ However, staffing ratios per stay or per person in the population are not very discrepant between the two countries.

Higher-paid staff. Employees of American hospitals could be paid more than similar employees at Canadian hospitals. We do not have data on wages. Hospital inputs other than personnel (for example, beds) tend to be traded in international markets, so their costs should not much differ between the two countries.

Administrative costs. Certain overhead or administrative costs may differ. For example, malpractice premiums no doubt are higher in the United States than in Canada. (Note, however, that one justification of the malpractice system is deterrence of negligent actions, which, if it were effective, ought to lower U.S. hospital costs relative to Canadian.) Administrative costs to cope with multiple sources of financing and various utilization review mechanisms also may be higher in the United States. However, it is unlikely that such differences could begin to account for the magnitude of the overall difference in spending, because total administrative and accounting costs are estimated to account for only 18 percent of U.S. expenditure on personal health care versus 8 percent in Canada.⁸

A Closer Look At Length-Of-Stay Differences

Our work points up the methodological difficulties of making comparisons across countries. Although our major conclusions do not appear sensitive to definitional differences, the difficulties in developing comparable definitions of hospitals may be a problem for more

detailed analysis of the two countries. Indeed, even within each country there are difficulties with hospital definition. For example, the figures often cited to show the decline in length-of-stay caused by PPS do not compare patients in the same hospitals over time.⁹ As a result, the well-known fall in length-of-stay resulting from PPS is overstated. If one includes patients in exempt hospitals in 1981 and 1984, average length-of-stay actually rose among those age sixty-five and over, from 9.9 days to 10.7 days in 1984; in 1985, however, length-of-stay fell to 9.5 days.¹⁰

Because of the importance of hospital definition in the number of long-stay patients and the importance of such patients in the overall length-of-stay figures, we compared the percentage of patients in the two countries with stays of over sixty days. Two conclusions emerged (Exhibit 6). First, U.S. data for all hospitals show a substantial increase in long-stay patients between 1981 and 1985. At the same time, long-stay patients in PPS-covered hospitals have decreased. (Of course, PPS gives a considerable reward for caring for long-stay patients in exempt hospitals or units.) Hence, average length-of-stay figures will be sensitive to the definition of hospital used and to the nature of patients in those hospitals.

Exhibit 6 Percentage Of Patients Over Age Sixty-Five Staying Over Sixty Days			
	1981	1984	1985
United States			
All hospitals	0.5	1.4	1.0
All excluding rehabilitation and long-term	—	0.4	0.2
Ontario ^a	2.7	3.0	2.9
Manitoba ^b	5.0	5.0	5.0

^aAll patients excluding rehabilitation and long-term.
^bExcludes stays in personal care units, geriatrics, and extended treatment hospitals.

Second, comparing the United States with Ontario and Manitoba shows that the proportion of patients with very long stays is considerably greater in Canada, especially in Manitoba; this proportion has been increasing in Ontario as well as in the United States (though not in Manitoba). The proportion of elderly with very long stays also has been increasing in British Columbia.¹¹ The reasons for this increase remain to be explored, but a small increase can cause a dramatic change in the average length-of-stay. For example, the average U.S. length-of-stay for patients staying over sixty days in 1985 was 130 days. Hence, a one-percentage-point increase in such patients will raise average length-of-stay 1.3 days. Given the increases in long-stay patients, government insurers might well want to investigate ways to reduce length-of-stay.

Although this is only a first look at comparing Canada and the United States, patients at U.S. hospitals appear to use either more inputs or more highly paid inputs (or both) than do patients at Canadian hospitals. This difference in intensity appears to account for the bulk of the difference in hospital spending between the two countries. If so, the ultimate question is what the United States buys with the additional intensity, if anything. That question can best be addressed with data that per-

tain to outcomes. The most readily available outcome data are mortality data, but they are too crude to answer the question. Readmissions data for complications and other poor outcomes following surgery are another available indicator of outcome. Lacking comprehensive measures of outcome, one reasonable next step is to pursue the type of analysis used here at the level of specific diseases and treatments.

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Perspectives: Canada

Split Vision: Interpreting Cross-Border Differences In Health Spending

ROBERT G. EVANS

FOR roughly two decades, North America has been the site of a vast social experiment on the effects of alternative ways of paying for health care. Conducted in real time, with entire populations and real bullets—no compensation if things work out badly—the “experiment” has nonetheless been quasi-controlled. Our two societies, Canada and the United States, are about as similar in language and culture as one can expect in an imperfect world, and have significant parallels in geography and historical experience. We have even had very similar medical care systems, at least at the beginning of the experiment.

Comparing The Two Approaches

The recognition that our divergent approaches offered a remarkable opportunity for better understanding of the effects of health policy emerged prominently at the Sun Valley Conference of 1974.¹ Theodore Marmor provided a particularly clear discussion of the “most similar case” approach to learning from cross-national experience, and has drawn heavily on the “North American experiment” in subsequent analyses of U.S. health insurance proposals.²

The quantitative analysis of comparative system performance, however, has had to wait upon both the accumulation of sufficient years of observation to carry conviction and the evolution of comprehensive and accessible databases describing the two systems in comparable terms. Only within the past five years has a substantial literature begun to develop, describing and interpreting the results to date. This paper by Joseph Newhouse, Geoffrey Anderson, and Leslie Roos makes a useful contribution to that literature, confirming results that had emerged from more general studies and highlighting significant issues for further exploration.

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The most obvious quantitative result from the “experiment” has been the stabilization of health expenditures in Canada, as a share of gross national product (GNP). Contrary to widespread impression, and generalization from elementary economic models, universal “free” care led not to cost explosion but to cost control. This is in marked contrast to experience both in the United States and Canada prior to 1971. Recent work by Tony Culyer shows that the Canadian record of cost control after 1971 also stands out against the background of the Organization for Economic Cooperation and Development (OECD) countries as a group, a more demanding standard than the United States alone.³

Awareness of this macroscale (and, initially, counter-intuitive) result grew gradually on both sides of the border in the late 1970s, along with the gap itself. By 1987, the difference in health spending had grown to nearly three percentage points of GNP—11.2 percent in the United States and 8.4 percent in Canada. The obvious questions are “Why?” and “How?”—the sources of difference in both an accounting and a policy sense—and “So what?”—what consequences flow from the divergent performance? Further research has targeted the cost differences in three major areas: costs of insurance administration, physicians’ fees, and the “intensity” of hospital servicing.⁴

Administrative costs of insurance. It was apparent from the outset to the designers of the Canadian plans that multiple, pluralistic insurers marketing a wide range of plans differing in depth and breadth of coverage would require a large “load factor”—the difference between premiums collected and benefits paid—to cover those design, administration, and marketing costs. Indeed, the Royal Commission on Health Services specifically mentioned the avoidance of these marketing and administration overheads as a significant advantage of a universal, comprehensive system.⁵ By the late 1980s, after nearly a decade of “market forces” in U.S. health care, about one-half of one percent of GNP in the United States is accounted for by the excess costs (relative to the

Canadian system) of paying for the reimbursement system itself.

Uwe Reinhardt refers to this quantity as the “B-Factor” in American health care: the costs of a (largely private) bureaucracy that neither provides care nor supports its provision.⁶ This “sector” of the U.S. health care industry is a relatively recent development; in 1960, U.S. and Canadian costs for administration and prepayment were roughly similar. From the perspective of health care, this part of the U.S./Canada cost discrepancy represents pure waste motion—pushing around bits of paper rather than providing health care. (One might argue that it represents the purchase of “variety,” but that is another story—and not a very plausible one).⁷

Physicians’ fees. The next major difference between the two systems has been in the growth of physicians’ fees. In the United States (as in Canada before public insurance), these fees have consistently escalated faster than general inflation rates. For the past twenty years, the bilateral bargaining process in Canada has kept fees more or less level in real terms.⁸ The interesting questions here relate to the ways in which physicians’ practice and billing patterns respond to either negotiated or independent fee-setting processes.

In aggregate, utilization differences between the countries appear small. Physicians in Canada have neither left the field nor emigrated; nor have they increased their billing rates to offset the effects of controls.⁹ Contrary to U.S. experience under the economic stabilization program (ESP), the ongoing process of fee negotiation in Canada has resulted in overall expenditure control.¹⁰ Nor has it been associated with any shortages of personnel or difficulties of access; doctor-to-population ratios in Canada are about the same as in the United States and growing about as fast.

It appears that the relative control of physicians’ fees has operated primarily as an “incomes policy,” limiting the transfer of wealth from the rest of society to physicians, or, in Reinhardt’s terms, influencing “the allocation of lifestyles to providers.”¹¹ Whether it has had any significant impact on styles and patterns of medical practice—the mix, as opposed to the overall volume, of medical activity—is an interesting question to which cross-border research might well contribute. Whether such fine-structure differences, if they should exist, would affect the health of our respective populations is a substantially more difficult question.

Hospital costs. The third major component of the cross-border cost differential, and the focus of the article by Newhouse, Anderson, and Roos, is the difference in hospital costs. In 1985, these were estimated at \$167.2 billion, or 4.18 percent of GNP, in the United States.¹² The corresponding estimate for Canada was 3.48 percent of GNP, nearly 20 percent below the U.S. ratio.¹³ This gap has emerged over the past two decades; in 1971, hospital expenditures were actually a larger percentage

of the Canadian GNP.

Previous analyses of this component of the Canada/United States discrepancy have focused on the comparison of trends within each country, rather than attempting to address levels of servicing directly. Alan Detsky showed that in Ontario, policies to limit the escalation of hospital costs had been successful but that their impact had been almost entirely on the “intensity of servicing” rather than on the escalation of costs of hospital inputs.¹⁴ The bundle of services—person hours of care, tests, procedures, drugs—received by patients in Ontario hospitals was rising less rapidly than in the United States. Indeed, over the period studied it hardly rose at all. Wages and other input costs, however, were rising about as fast (relative to general inflation rates) as in the United States.

Similar findings were subsequently reported for the whole of Canada.¹⁵ When expenditures per capita are deflated by an index of hospital input prices (wages and other things), the resulting “intensity measure” (which includes changes in both admissions or patient days per capita, and servicing rates per admission or patient day) has escalated much more slowly in Canada than in the United States, both after, and even before, 1971. (Public hospital, as opposed to medical, insurance was universal in Canada by 1961.)

Since the expenditure differences in hospitals appear to be associated with real differences in servicing rates rather than simply bureaucratic overhead or fee levels, the question naturally arises as to whether the Canadian experience represents “underservicing”—the failure to provide patients with potentially effective interventions. Conversely, does the increasing “servicing intensity” in the American system reflect increasing provision of essentially ineffective services?

Comparing Levels Of Expenditure

Unlike previous investigators, Newhouse and colleagues address the comparative levels of expenditure in each country. Carried through consistently, this approach would permit the direct comparison of servicing intensities, rather than merely their rates of change. This, however, would require indices of hospital input prices in each country, which could be linked across the border at a point in time, rather than simply each set equal to 100.0 in a common base year.

Such comparative hospital input price data do not currently exist. Instead, the authors have taken per capita hospital expenditures in each country’s own currency, converted the American series to 1985 dollars by using the gross national expenditure (GNE) consumption deflator, and then converted the Canadian series to U.S. dollars by using the exchange rate in each year. The floating exchange rate is assigned double duty, both converting currencies at a point in time and reflecting the

discrepancies in the two countries' inflation rates over time.

Unfortunately, the procedure fails, for two reasons. First, the Canada/U.S. exchange rate has fluctuated widely over this period for reasons and in ways quite unconnected with relative inflation rates. Over some (undefined) long run, movements in exchange rates should reflect countries' relative inflation rates; in North America and between 1981 and 1985, they have not. A better procedure would have been to adjust each country's per capita expenditure by its own price index, and then apply the OECD estimates of the purchasing power parity (PPP) exchange rate for 1985 to the two currencies. As it is, the time series estimates of Canadian hospital expenditure presented in Exhibit 1 of the article are meaningless.

Second, if one is to compare servicing intensity, one must deflate by indices of hospital input prices. There is no reason to believe that such prices bear the same relationship to general consumer prices in each country. The authors' procedure might serve instead to measure the relative amount of generalized purchasing power given up, in each country, to the hospital system, rather than the real volume of hospital services bought. But then, what has been gained over the percent-of-GNP comparison?

In fact, however, the principal thrust of the article by Newhouse and colleagues is not affected by the problems in converting across currencies. The estimates in Exhibit 1 are not used elsewhere, except in the very general sense that the Canada/United States discrepancy is A Big Number, which is certainly true. But it would be unfortunate if their nice round "50 percent" figure were taken too seriously. It is clearly too large. The current dollar expenditures on hospitals per capita in the two countries in 1985 are \$676 (U.S.) and \$633 (Canadian)—a difference of 6.8 percent. If \$0.85 U.S. equals \$1 Canadian, the OECD-estimated PPP exchange rate for that year, the differential is 25.6 percent—still A Big Number, but much less dramatic. A good deal more work is necessary to develop a reliable time series of comparative expenditure levels, whether in terms of general purchasing power or *a fortiori* in terms of real "servicing intensity."

The authors approach this Big Number with a combination of utilization analysis and speculation, and it is the former that is the heart of their article. They focus on the population over age sixty-five, to exploit the American Medicare database. Unfortunately, since as they point out the Canadian financial system does not track costs per patient, one cannot assume that the differential in costs for the entire population applies to the over-sixty-five subgroup as well.

Comparing selected jurisdictions, they find that lengths-of-stay are substantially higher north of the border, and that there is no evidence of lower admission rates or less severe cases as measured by diagnosis-

related group (DRG) indices. This comparative case-mix analysis is particularly interesting, and is the authors' principal contribution. It reinforces the view that the Canada/United States cost differential is located in patterns of servicing within hospitals, not in different patterns or rates of admission or discharge.

Further Research Opportunities

Length-of-stay differences. There remain a couple of important points for further research. First, the large difference in lengths-of-stay is quite worrisome. As the authors are aware, *de facto* long-term cases are much more likely to be included in acute care beds in the Canadian hospital system, for reasons solidly rooted in the differences in the financing system. They have tried to remove these cases, both by eliminating patients designated as other than acute care and by trimming lengths-of-stay at sixty days. The adequacy of these adjustments, however, depends on the administrative arrangements in the particular jurisdictions studied. In British Columbia, which has been quite aggressive in moving *de facto* long-term cases out of acute beds, the average length-of-stay for acute patients over age sixty-five is about 9.5 days (in fiscal 1985-1986).

Further work is clearly necessary to ensure that the Canadian data are not still "contaminated" by nonacute cases. This is of particular importance, since servicing intensity tends to be negatively correlated with length-of-stay. The increasingly divergent trends in intensity in the two systems, found by other researchers, no doubt reflect in part the increasing proportion of the Canadian acute hospital workload that is (however labeled) long-term care.¹⁶

Measuring "intensity." The second major point is that "intensity" measures different things in the two systems. The complex payment system in the United States requires hospitals to maintain a much larger administrative and financial staff to bill patients and insurers, determine eligibility, and cope with disputes. The demands of "competition" are adding to the costs of marketing the hospitals' products. These costs have no counterpart in the Canadian system and no obvious benefit to patients, although they are included in hospital expenditures rather than in the overhead costs of insurance and prepayment administration.

The authors consider this point and reject it as a major contributor to the cost differential. Yet they quote David Himmelstein and Steffie Woolhandler, who provide a rough estimate of relative costs of administration in American and Canadian hospitals.¹⁷ They estimate that in 1983, fully 10 percent of American hospital costs were "administrative waste" relative to what they might have been with a Canadian-style system.

A possible source of confusion is that this figure is a share of American costs, whereas the "50 percent" differential is on a Canadian denominator. Himmelstein and

Woolhandler's 10 percent represents not one-fifth but about 30 percent of the differential reported by Newhouse and colleagues. Furthermore, if the true Canada/United States differential is in fact closer to 25 percent, then the share accounted for by different internal administration costs is about half. No one has ever suggested that the whole differential was administrative, but half of A Big Number is also A Big Number.

Relative administrative costs. Himmelstein and Woolhandler's estimate is clearly a first cut, based on a number of diverse sources. But it matches, in order of magnitude, the impressions of hospital administrators with experience on both sides of the border. The authors' dismissal of this issue is clearly wrong, and a much more detailed analysis of relative administrative costs would be well worthwhile. If we are concerned to use comparative experience to address questions of relative "underfunding" or "overfunding," we presumably wish to compare the actual use of health care by comparable patients. Payments to accountants and public relations specialists (and even economists), as hospitals respond to the vagaries of the reimbursement system, are not part of this computation.

At the end of the day, however, all such aggregate comparisons can only be indicative, pointing beyond themselves. The authors' call for more detailed studies of the actual process of care in the different systems, for similar types of problems, seems very clearly the right way to go, not least because such studies can be linked directly to comparative measures of outcomes. The answers at the aggregate level are already mostly in; it is time to look for God in the details. In the process, however, we must take particular care both to ensure that the patients studied are indeed comparable and that other forms of expenditure, unrelated to patient care, are not bootlegged into the comparison.

NOTES

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Perspectives: United States

Learning From the Canadian Experience

VICTOR R. FUCHS

SOMETIME during the next decade the United States will probably embark on major reform of our pluralistic system of health care finance. The growth of the uninsured and the failure of the so-called competition revolution of the 1980s to stem the rise in health care spending are just two of the factors pushing the nation toward more radical change.¹ In seeking to develop new approaches, health policy experts inevitably will attempt to draw on the experiences of other countries, especially those such as Canada that have managed to implement universal coverage while simultaneously containing costs well below U.S. levels.

In doing so, it would be wise to resist simplistic notions about the easy transfer of health care systems across national boundaries. "The organization of medicine," law professor Walton H. Hamilton wrote in 1930, "is not a thing apart which can be subjected to study in isolation. It is an aspect of culture, whose arrangements are inseparable from the general organization of society." But even if it is impossible to reproduce another country's experience, it should be possible to learn from it. The potential for learning is particularly great in a comparison of Canada and the United States because of both the differences and the similarities between the two countries.

In 1986, Canadians spent approximately 8.5 percent of their gross national product (GNP) on health care, while Americans spent approximately 10.9 percent. If U.S. spending had been held to the Canadian *ratio*, the savings would have amounted to about \$100 billion. This large difference between Canada and the United States has emerged only since the 1970s. Before then, the percentages of GNP spent for health care were similar in the two countries. This was not surprising because the United States and Canada are similar in many respects, including training of physicians and other health professionals, political and economic institutions, and popular

culture. Thus, the recent divergence in spending provides an unusual natural experiment.

The exploratory study of hospital spending by Joseph Newhouse, Geoffrey Anderson, and Leslie Roos draws on that experiment to compare hospital utilization by patients age sixty-five years and over in the United States and Canada. Admission rates and case-mix indices appear to be similar in the two countries; length-of-stay is much longer in Canada, but cost per case (and cost per enrolled person) is much lower. There is little reason to question the authors' principal conclusions; therefore, I devote the balance of this commentary to certain conceptual and analytical issues concerning international comparisons of health care.

Economic Accounting

Newhouse and colleagues focus on the differential in expenditures per capita in U.S. dollars; they transform Canadian expenditures into U.S. dollars through an exchange rate. One possible problem with this approach is the determination of the appropriate rate. Most economists believe that, in the long run, a free-market rate reflects differences in the price levels between the two countries (at least for internationally traded goods). In the short run, however, the market rate can be affected by capital flows, foreign exchange speculation, and other factors that are irrelevant to a comparison of health care systems. Use of an inappropriate exchange rate will distort international comparisons.

Consider, for instance, three possible comparisons of per capita expenditures for health care in the United States and Canada in 1980.² Basing a comparison on the market rate of exchange indicates that spending is 38 percent higher in the United States. If the comparison is based on an exchange rate obtained by comparing the prices of all goods and services produced in the two countries (purchasing power parity, or PPP), the differential is only 27 percent. A third possible comparison, based on an exchange rate derived from only health-sector prices (health purchasing power parity) shows a differential of only 22 percent. The fact that the third

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differential is smaller than the second indicates that, relative to other goods and services, health care prices are lower in Canada than in the United States.

Sharp fluctuations in the Canadian/U.S. market exchange rate in recent years indicate that choice of the correct rate continues to be a problem of considerable practical significance. Between February 1986 and July 1988, the number of Canadian dollars needed to purchase one U.S. dollar fell by 19 percent. In the first seven months of 1988 alone, the number of Canadian dollars needed to buy one U.S. dollar fell by 7 percent. The reasons for this appreciation in the value of the Canadian dollar are not known precisely, but probably have little to do with changes in health care. Nevertheless, comparisons based on the market rate would show sharp fluctuations in the U.S./Canadian differential in expenditures for health care.³

One way of avoiding the exchange rate problem is to concentrate on the differential in health care expenditures as a percentage of gross national product ($\frac{X}{GNP}$), with each country's values calculated in its own currency. This differential, in an accounting sense, must result from differences in one or more of the following three variables: the quantity of services per capita ($\frac{Q}{POP}$); the inputs required per quantity of service ($\frac{1}{Q}$); and the prices of health care inputs relative to GNP per capita ($\frac{P}{GNP/POP}$). That is,

$$\frac{X}{GNP} \equiv \frac{Q}{POP} \cdot \frac{1}{Q} \cdot \frac{P}{GNP/POP}$$

If we think of each term as the ratio of U.S. to Canada, the equation tells us that the U.S./Canada ratio of the share of GNP devoted to health care is identically equal to the product of the three terms. Because the identity is multiplicative, the relationship between the logarithms of the U.S./Canada ratios is additive. That is,

$$\ln \frac{X}{GNP} \equiv \ln \frac{Q}{POP} + \ln \frac{1}{Q} + \ln \frac{P}{GNP/POP}$$

Thus, it is possible in principle to decompose exactly the U.S./Canada differential and to show how much is accounted for by differences in services per capita, differences in productive efficiency, and differences in input prices (relative to GNP per capita).

Behavioral Explanations

A statistical decomposition along the lines outlined above would provide much useful information about the differences between the Canadian and U.S. health care systems. But it would be only a first step. Economic accounting needs to be supplemented by behavioral explanations. I believe that all three variables on the right-hand side of the equation contribute to the U.S./Canadian differential, and it would be of tremendous theoretical and practical importance to understand what behavioral mechanisms are responsible for the national differences in those variables.

Consider first the question of quantity of services per capita. If Canadians consume fewer services, what in the Canadian system constrains utilization? Some of the

most popular explanations that have been offered with respect to U.S. health care expenditures fall flat if applied to the Canadian scene. For instance, Canadian patients are virtually fully insured; deductibles and coinsurance are clearly not the mechanism of restraint. Moreover, Canadian physicians are mostly reimbursed on a fee-for-service basis; there is very little use made of prepaid group practice, capitation, and other financial mechanisms that are relied on in the United States to restrain utilization by changing physician behavior. There are, however, government sanctions, actual or potential, that may cause Canadian physicians to limit their use of tests and other procedures. The most readily identifiable source of restraint on the Canadian scene is the fact that most of the funds for health care come from a single source. With hospital budgets set in advance, it is very difficult for hospital administrators, physicians, patients, or anyone else to spend more than the budgeted amount. A second potential source of restraint on utilization in the Canadian system is the much lower ratio of specialists to general practitioners. By virtue of their training, knowledge, inclination, and interests, specialists tend to order more services.

The smaller number of specialists in Canada also may contribute to the second term, namely, fewer inputs for any given volume of services. It is well known that in the United States the large number of surgeons and other specialists contributes to a low average workload. It is possible that workloads are higher in Canada; that is, highly trained health professionals may be used more efficiently. Canada also probably saves on the use of other personnel to enhance production efficiency. For instance, there must be many fewer people employed in health care in Canada to sell and administer insurance plans, and the Canadian system probably requires fewer employees for billing, utilization review, and other administrative and marketing functions.

With respect to the third term, it seems likely that the Canadian provincial governments, with their monopsony power in the purchase of medical care, can use that power to drive down the prices of inputs relative to the prices of other goods and services in Canada. This could show up in the prices paid to physicians, to drug companies, and to other suppliers of goods and services.

Consequences

Economic accounting and behavioral explanations are two important elements in a comparison of the two health care systems. The third is to understand the consequences of differences in behavior. If Canadians receive fewer health services than Americans, what effect does that have on health or other aspects of well-being? Perhaps the services that are not received are of so little value to the patients that there are no discernible effects on mortality or morbidity. This question is, in principle, answerable, but there are others that will prove to be more difficult to investigate. Once one moves from fairly objective measures of health status to more subjective

questions about consumer satisfaction, the conceptual problems are quite severe.

Consider, for instance, the problem of evaluating the differences in length-of-stay between the two countries. Is hospital output to be measured purely in terms of changes in medical status, or are amenities and conveniences also to be considered? From an economic perspective, the latter should be included if they are of value to the patient, that is, if the patient would be willing to pay something for them. When the length-of-stay differs appreciably, as it does between Canada and the United States, the conceptual problem is particularly perplexing, as can be seen from the following example.

Suppose a Canadian patient and an American patient enter their respective hospitals with identical medical conditions, are treated successfully, and upon discharge their medical status is again identical. Further suppose that the Canadian patient stayed nine days and the American patient, six days. Shall we credit the hospitals with the same output? If change in medical status is the only criterion, the answer is obviously yes. But viewed from the patient's perspective, the outputs need not be the same. If the patient values the extra three days in the hospital (that is, would be willing to pay something to be allowed to stay), the hospital with the longer stay should be credited with more output. On the other hand, if the patient prefers getting out in six rather than nine days (that is, would be willing to pay something not to have to stay the extra three days) the hospital with the shorter stay should be credited with more output. We know very little about the preferences of patients with respect to this question; furthermore, different patients may have different preferences.

It would also be interesting to know how the cost of producing an identical change in medical status varies with the length-of-stay. The longer stay may cost the

hospital more because of additional expenses for room and board. On the other hand, it is also possible that the shorter stay costs more (to achieve the same medical condition at discharge) because services must be delivered intensively. Moreover, since the two hospitals probably will be using different combinations of inputs, the cost comparison may yield ambiguous results if the relative prices of inputs differ in the two countries. Given a certain combination of preferences and relative prices, it may be more efficient for the American hospital to discharge after six days and more efficient for the Canadian hospital to discharge after nine.

The differences in health care systems may have other consequences: for medical education, medical research, the recruitment of young women and men into medicine, and the like. A full comparison should consider these areas as well. In short, there is an enormous amount of work that could be done, and in my opinion should be done, to capitalize on the most interesting natural experiment in health care of recent decades: the different paths taken in Canada and the United States.

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NOTES

1. V.R. Fuchs, "The Counterrevolution in Health Care Financing," *The New England Journal of Medicine* (30 April 1987):1154-1156; and V.R. Fuchs, "The 'Competition Revolution' in Health Care," *Health Affairs* (Summer 1988):5-24.
2. U.S. Department of Commerce, Bureau of the Census, *Statistical Abstract of the United States 1988* (Washington, D.C.: U.S. GPO, 1988), 804; and Organization for Economic Cooperation and Development, *Financing and Delivering Health Care: A Comparative Analysis of OECD Countries*, Social Policy Studies no. 4 (Paris:OECD, 1987), 21, Table 3.
3. J.F. Burns, "Exchange Rate Keeps Canadian Industry on Pins and Needles," *The New York Times*, 1 August 1988, C-8Z.

Defending the U.S. Approach to Health Spending

SAMUEL A. MITCHELL

DESPITE comparable admission rates and case-mix indices, the United States—according to Joseph Newhouse, Geoffrey Anderson, and Leslie Roos—spent 50 percent more per person over age sixty-five on hospital services than Canada in the early 1980s. The methodology they employed in arriving at this finding was meticulous and complete in its dedication to objectivity, and the necessary computational judgments seem reasonable. Consequently, the study results can safely be shifted from the category of hypothesis to the category of strong presumption.

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The key inference of these findings is that "the difference in hospital spending between the countries . . . must be accounted for primarily by differences in the cost of a 'case-mix unit' per beneficiary." The questions of main interest to policymakers are: (1) Why does this difference occur; (2) Is the difference "good" or "bad"; and (3) What, if anything, should be done?

What Accounts For The Difference?

Advocates of the Canadian system or, conversely, critics of the American system like to argue that the Canadian government's monopsonistic control over health spending greatly minimizes the waste allegedly rampant in U.S. hospitals. This inference is facile and

wrong, especially in the late 1980s when average hospital Medicare margins have been steadily declining and are expected to disappear in fiscal year 1988.¹ No hospital wants to lose money; thus it is unlikely that administrators, finding themselves under increasingly intense financial pressure, have failed to do all they can to minimize inefficiency.

A full analysis of why case-mix-adjusted hospital costs per beneficiary were so much higher in the United States should consider the following: (1) Wage differences exist among the two systems. Unfortunately, as Newhouse and colleagues note, the necessary data are not available. (2) There also are differences in the rate of development and diffusion of new technology. It would be very illuminating to look at comparative rates of lens implants, organ transplants, angioplasty, and the provision of state-of-the-art diagnostic procedures per 1,000 population. We would not be surprised if rates in the United States were significantly higher. (3) Differences exist in income and the income elasticity of demand. Americans on average are richer than Canadians; richer people tend to spend more of their marginal income in health care. Moreover, Americans' income elasticity of demand for health care may be greater than that of Canadians.

(4) The two cultures possess different values. The strong tradition in the United States of favoring the interests of the individual over those of society means that we condone, even insist upon, heroic measures to extend life or improve the quality of life, even if the likely improvement is slight and the long-term prognosis is impervious to treatment, no matter how elaborate. Thus, American physicians tend to fight disease, disability, and the prospect of death aggressively with every tool modern technology makes available. The "fix the problem at all costs" approach produces an occasional miracle, but it is very expensive, and the incremental improvement in health status often is very slight while the cost often is very high.

(5) Physician payment mechanisms differ as well. Physicians in the United States, for the most part, have been paid more for doing more, and the return on their time is higher if they perform a procedure than if they use their cognitive skills. Since procedures often require hospital care (more so during the time period covered by the study—1981, 1984, and 1985—than today), incentives favoring procedures translate into higher hospital expenditures. Canadian physicians, by contrast, during the years studied had less leeway to make more by doing more, thereby driving up hospital costs. They were operating under a system of fee schedules and overall provincial limits on health spending. Moreover, extra billing of patients by physicians was relatively infrequent. In fact, as John Iglehart has noted, in 1984 the Canadian Parliament unanimously passed legislation providing that "provinces that imposed, or permitted physicians to impose, direct charges on patients would lose federal grants dollar for dollar in proportion to such charges."²

The relative importance of these and other factors accounting for differences in hospital spending per comparable case is not known, but it does seem reasonable to argue that the simplistic notion that the American hospital system is much more wasteful, as its critics contend, is at best misleading. An appreciation of the values and incentives affecting physician decision making, which in turn importantly affect hospital costs, is a prerequisite for developing payment policies that best serve the *American* public's interest.

Assessing The Differences

Newhouse, Anderson, and Roos obliquely address the question of whether the U.S./Canadian differences are "good" or "bad" when they say that "the question (of what, if anything, the United States buys with the additional intensity of care) can best be addressed with data that pertain to outcomes." We do not know how outcomes in the United States and Canada compare. However, even if there is no difference in measurable outcomes such as mortality rates, life expectancy, preventable treatment errors, and so on, there are other important but perhaps impossible-to-measure components of value that must be considered as well. To an individual patient, an extra dollar of hospital care spent in his or her behalf may not improve the ultimate outcome, but still could have great value if treatment did nothing more than increase comfort, reduce anxiety, enhance the ability to function independently, or reduce, even slightly, the probability of an adverse outcome. Americans may not live longer than Canadians, but our expensive health care system may enable those who have been ill to live better. And it may offer valuable assurances to those of us who are not patients, but could be, that top-of-the-line care will be available to us immediately on demand. In short, before reaching conclusions about the value of hospital care relative to the cost, it is necessary to consider all elements of satisfaction as perceived by both actual and potential patients. The ultimate test of the "goodness" or "badness" of American versus Canadian hospital spending levels should, I believe, turn on which process for arriving at expenditure decisions best reveals the value of hospital care not just to those who happen to be patients, but to the rest of us as well.

The problem of maximizing satisfaction relative to cost is immensely complicated by the fact that the same person's preferences differ, depending on whether that person is a particular beneficiary of the health care system—a patient—or an anonymous financier of health care either as a taxpayer or a consumer of goods and services, part of whose cost is the cost of employee health care. Because so much hospital care is paid for by a third party, the usual measure of consumer perceptions of value relative to cost—the price the beneficiary of a service is willing to pay—is not a useful guide to measuring satisfaction relative to cost. Since beneficiaries typically do not pay the bills, they are largely indifferent about how large the bills are. The fundamental policy

issue, then, is this: if the pricing process that occurs between buyers and sellers in a properly functioning market is not available, what other mechanism will best reveal those cost/service tradeoffs that maximize satisfaction per dollar spent?

Alternatives For Action

Canada has decided that government monopsony is best. Power to set overall spending limits is concentrated in the hands of government experts. Budget-setting officials are only very remotely accountable for the effects of their decisions on individual patients, but the effects of their decisions on government spending are highly visible. Thus, over time, the interests of the public as taxpayers will dominate. Because feedback as to the consequences of their decision is slow and indirect, and there are few incentives to maximize satisfaction, I question whether centralizing decision-making authority over total spending is the best possible way of revealing what level and mix of spending creates the greatest satisfaction.

On the other hand, the United States, with its tradition of favoring the immediate interests of the individual at all costs, has tried to avoid altogether the problem of making painful choices between controlling costs and giving

individual patients the best of everything. The consensus now, however, is that we no longer have this luxury.

I believe that for the United States there is a better alternative than adopting the monopsonistic Canadian system. The decentralized American payment system is more in keeping with the high value Americans put on holding payers accountable to the wishes of the insured. However, it heretofore has lacked the essential ingredient for striking the right balance between accommodating the wishes of patients and keeping costs within the constraints set by whoever is paying the bills. This missing ingredient is information as to what works (effectiveness) and information at the local level as to which providers not only do the right things, but do them most efficiently. Newhouse, Anderson, and Roos have given us a solid base of comparative data, but it should not be inferred from their findings that the Canadian system is better or that the United States should adopt similar payment mechanisms.

NOTES

1. A. Dobson, "Letter to the Honorable Martin Frost" (Washington, D.C.: Consolidated Consulting Group, 25 August 1988).
2. J.K. Iglehart, "Health Policy Report: Canada's Health Care System," *The New England Journal of Medicine* 315, no. 3(1988):207.

Fixing an Inefficient System

PETE STARK

NO observer of the American health care delivery system should be surprised by the results of the study by Joseph Newhouse, Geoffrey Anderson, and Leslie Roos on trends in hospital spending in the United States and Canada. Their conclusions confirm our suspicions that it is possible to manage health care delivery more efficiently without impairing quality.

The author's key findings support four critical conclusions about the American health care delivery system: (1) Contrary to the contentions of the hospital industry, U.S. hospitals are, on the whole, very generously supported. (2) The U.S. hospital system is inefficient. (3) The higher costs associated with hospital care in the United States are making universal coverage of our population difficult to achieve. (4) Substantial economies remain possible without fear of affecting outcomes.

The U.S. hospital system is generously supported. We devote 4.4 percent of gross national product (GNP) to hospital care, while Canada and the Federal Republic of Germany devote only 3.5 percent and 2.7 percent, respec-

tively. Yet there is no evidence that the Canadians and the West Germans do not have high-quality systems, and, in fact, their mortality statistics are better than those of the United States.

The U.S. hospital system is still an extremely inefficient industry. On a given day, there are 349,146 empty, staffed hospital beds in this country—over a third of the total staffed beds. If we add the beds that are built but not staffed, almost half the beds in this country are unused. In addition to empty beds, virtually every city boasts underused specialized services, such as cardiac surgery, where not enough work is done to maintain competency. And because of this amount of waste we face an approximate 11 percent increase in hospital capital costs year after year.

Canada, on the other hand, enjoys a hospital occupancy rate of 84 percent. The reason for this significantly higher rate is clear. The Canadians do not hand their hospitals a blank check and allow them to build facilities whether they are needed or not, as do we. Canada establishes a capital budget each year at the provincial government level and carefully plans how to allocate resources within that budget so that each community has the health care facilities that it needs and that the nation can

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afford.

The opportunity costs associated with the higher level of expenditures per hospital admission in the United States are substantial. Most importantly, if our expenditures were more in line with the Canadians', we could afford coverage for those who lack health insurance. All Canadians have health insurance. In the United States, thirty-seven million Americans are uninsured, and another seven to ten million are inadequately covered. Two-thirds of uninsured Americans are full-time workers or their dependents. The inadequacy of our health insurance system has resulted in a gross maldistribution of resources in American hospitals. Our present financing system is assuring that the rich get richer and the poor get poorer.

Hospitals that serve those covered by private health insurance and Medicare are overfunded, while those serving the poor are underfunded. The affluent hospitals can afford to purchase the latest technology and to renovate their facilities regularly. Meanwhile, the public and private hospitals serving the poor are falling behind and falling apart. Our response to the current situation

must focus on the goal of assuring access to needed services on a cost-effective basis. The study by Newhouse and colleagues makes clear that we need not raise public and private payments to hospitals at excessive rates simply because hospitals continue to spend themselves into tight financial situations. In fact, given the inefficiency of the system that this article highlights, further cuts can safely be made if the cuts are targeted to the inefficient parts of the system. For example, we can reduce the rate of growth in capital payments and reduce payments for support of teaching programs that are training specialists the country does not need.

The Canadians view health care as a service to which every member of society must have access. In contrast, many in our society see health care primarily as the buying and selling of a commodity by independent entities. As I see it, the Canadian perspective is more appropriate. The list of unmet health needs in our nation is a long and disgraceful one to which we must find ways to respond. The Canadian success in holding down costs while providing universal access offers a lesson for all.

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Guest Editorial

Residency Requirements in Medicine and the Community Hospital

With the recent passage of new residency requirements for accreditation in internal medicine and its subspecialties, we are entering a new era in the role of the community hospital in internal medicine education and training. For many years the community hospitals have played a major part in training internists to enter the private practice of internal medicine and to be the deliverers of "primary care" to the communities they serve. The new accreditation requirements relate to the milieu that should exist in teaching hospitals. They include the following:

- that the institution demonstrate educational and research activities equivalent in quality to those characteristic of academic medical centers affiliated with LCME-accredited medical schools;
- that the program director be a full-time institutional appointee and that there must be at least four additional full-time faculty members who dedicate substantial effort to the training program;
- that a qualified individual, preferably full-time, should be responsible for teaching activities in each of the recognized specialties;
- that at least two additional accredited residencies be sponsored by the institution;
- that the teaching responsibilities of residents must not involve students who require special remedial work and extensive supervision, as may be the case with students from medical schools not accredited by the LCME;
- that special care unit experience should not exceed six months in three years of training;
- that the performance of its graduates on the certifying examination of the American Board of Internal Medicine may result in a loss of accreditation for the program if the pass rate of the program's graduates on examination for a recent defined three-year period is less than 50%, or fewer than 75% of those completing their training in the program taking the examination. In the subspecialties, additional requirements for full-time direction of a program offering a fellowship as well as existence of three or more fellowship programs and clinical research are requirements.

It is clear that these requirements are directed toward removing accreditation from a large number of pro-

grams that utilize residents for fulfilling the service responsibilities in the hospital. It also becomes clear that the affiliating university must play a major role in the community hospitals that it wishes to support.

The first and most important requirement in this new relationship is for the university to decide if it wishes to involve itself with community hospitals. If the answer to this question is affirmative, the university must define this relationship, which may represent one of several models. In one model the university may integrate the community hospital into its training program and rotate its residents to the community hospital for an experience that may be unavailable in the medical center setting. Such experiences might include general medical service rotations, as well as continuity clinics or primary care office rotations. An alternative would be for the medical school to lend academic support to the community hospital and assist in the definition of a curriculum in that hospital. Further, by assisting the community hospital in recruitment of residents and then permitting those residents to rotate to the medical center for experiences unavailable to them in the community hospital, the university would be demonstrating a large measure of support and commitment.

One clear issue that remains to be recognized by the university is that the continuity of care and primary care experiences in the community can be far more meaningful than those the resident can acquire in the tertiary care medical center setting. It should be the university's responsibility to work with the faculty based at the community hospital to organize and coordinate, through a well defined curriculum, the way in which this role can be fulfilled by the community hospital.

Another key point in defining the relationship between the university and the community hospital relates to the identification of faculty. If the medical school does not recognize that there are physicians in the community hospital with a true commitment to teaching, clinical research, and patient care, and is not prepared to reward those individuals with appropriate academic appointments, then it is highly unlikely that the relationships between the two institutions will be successful.

An additional, and perhaps the most critical component, involves the responsibilities of the administration and the board of trustees of the community hospital. The era that we are entering requires that they reaffirm their commitment to the value of the teaching program to the hospital. Without the active support of both administration and trustees, the medical staff will soon become disenchanted with the hospital's role in teaching. There must be a commitment for financial support that is active and ongoing if teaching programs are to continue to

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thrive with these new requirements being placed on them by regulatory agencies, as well as the new difficulties in funding. I believe we will see many community hospitals, after careful introspection, abandon their teaching activities. This has some negative consequences including a lack of staff renewal in some communities, a delay in the transfer of technology and information from the medical center to the community hospital, and, most importantly, a decline in the quality of care for the patients being served. It is our responsibility as educators and

program directors to be sure that our medical staff, administration, trustees, and the community which we serve understand the implications of these new requirements and the demands that they will place on our hospitals.

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50 Years Ago

From the *Journal of the Connecticut State Medical Society* March 1939

A Full Time Secretary

At its Annual Meeting in May 1936 the House of Delegates of the Connecticut State Medical Society took a step which will long remain as an outstanding evidence of progress. It had been apparent to many in the Society for a few years prior to that date that there was a need for more assistance in the administrative work of the Society. The so-called radical, progressive element advocated a full time secretary with sufficient office assistance to cope properly with the increasing problems confronting organized medicine in the State. The more conservative reactionary members opposed any such change and were content to carry on with a part time member Secretary doing the work as best he could and where best he could. After the situation had been carefully studied by a special committee appointed by the President, a compromise plan was proposed and accepted by the House of Delegates. By this plan there were established three Secretaries, one of these being an Administrative Secretary, who would be a member of the Society on a part time basis, with an office equipped with a full time stenographer. The remainder of the Secretarial triumvirate included a Legislative Secretary and a Secretary on Scientific Work to act as Editor of the Journal.

This suggested change in administrative personnel was accepted by the House of Delegates and an increase in annual dues from four to five dollars followed. The new incumbent of the office of Administrative Secretary was our present Executive Secretary, Dr. Creighton Barker. The duties of this secretary have increased like the proverbial snowball and following the annual meeting of the Society in June 1938 we find him assuming, in addition to his other duties, those of Legislative Secretary. In the three years the work of the Executive Secretary's office was likewise increased beyond the conception of most of the members so that at the present time there are required in that office two full time stenographers as well as additional assistance at certain periods of the year. The budget of the Society, to keep pace with the require-

ments of the administrative needs and of the monthly Journal, has been increased from \$7,125.00 for the year 1936-1937 to \$12,500.00 for the year 1938-1939. All this is in keeping with changes in the practice of medicine and in the proper administration of the duties which organized medicine has found itself obligated to assume throughout the entire country. It is not a question of how cheaply a State Medical Society can be managed today but of how efficiently it can carry on for the best interests of its membership. For several months it has been apparent to many who are cognizant of the facts that the demands made upon our part time Executive Secretary are such that it is physically impossible for one individual to meet them and at the same time pursue a private practice. His duties carry him far afield, for beside frequent trips to Hartford to attend hearings on bills pertinent to the practice of medicine or speaking in Bridgeport, Hartford, Waterbury and New London on the vital issues of medicine as they exist today, he is called to National Medical headquarters in Chicago, or to Federal headquarters in Washington. His ear must be ever on the ground and his finger on the pulse to detect every move in this swiftly changing order. If medicine is at the cross roads, as Dr. Van Etten, former speaker of A.M.A. House of Delegates say it is, such an office or person is indispensable for the state organization and its individual members.

In many State Medical societies where there is large membership there will be found a full time secretary who receives a recompense commensurate with his services. Our Society must take a similar step if it is to continue to develop as it has during the last three years. Therefore, the Council is considering that the budget be increased to care for these needed developments. However, the ultimate decision must rest with each member through the component County Associations and through the House of Delegates of the State Society.

The Editor
Stanley B. Weld, M.D.

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Julia B. Sabetta, M.D., Westport

A MESSAGE FROM THE PRESIDENT

The 197th Annual Meeting of the Connecticut State Medical Society is planned for May 10th and 11th this year. The House of Delegates will meet on Wednesday, May 10th in an all day session. The progressively more difficult issues facing medicine today will be addressed including such timely subjects as RBRVS, AIDS, Universal Healthcare, and the incremental incursion of limited licensed practitioners into the practice of medicine. Updates on CMIC, M.D. Health Plan, and CPRO will be presented. Any interested physician members may attend and speak at reference committee hearings as well as observe the very democratic action of the House of Delegates as it comes to grips with these thorny issues. I believe it is a great learning experience for any physician member.

Included at the House of Delegates meeting will be the inauguration of our next president, Roger S. Beck, M.D. of Hartford, whose address should give us further direction for the year to follow. A reception in Dr. Beck's honor will be held at the close of the House of Delegates.

On Thursday, May 11th, the sections will meet both morning and afternoon with their own programs. For anyone interested, an intriguing 10:30 A.M. program on the burgeoning "transplantation industry" will be presented. Dr. William Marks, Associate Professor of Surgery from the Transplantation Unit at Yale, will discuss the growth of transplantation services, their distribution and cost, and their integration into the fabric of medical practice. Dr. Robert Levine, Professor of Medicine and Chairman of the Human Investigation Committee at Yale, will discuss some of the ethical and social issues which derive from the practice of transplantation of tissues. This session will be followed by a luncheon. Please utilize the appropriate tear outs and take advantage of what I feel is one of the many important benefits provided by your Society.

Norman A. Zlotsky, M.D.

**GENERAL INFORMATION
READ CAREFULLY**

REGISTRATION

The registration desk will be located in the lobby of the Inn and everyone attending the meeting is requested to register. There will be no charge for registration.

PARKING

There are ample parking facilities

TELEPHONE

Telephone messages will be received at Meriden, 238-2380.

LUNCHEON

Luncheon will be served Poolside. MEMBERS OF THE SOCIETY WILL BE GUESTS OF THE SOCIETY. ADMISSION TO THE LUNCHEON WILL BE BY ADVANCE RESERVATION ONLY. If you plan to attend the luncheon, it is the utmost importance that the card enclosed with the program be returned at once.

HOTEL ACCOMMODATIONS

Persons who wish to stay overnight at the Inn should make room reservations as soon as possible. Please indicate in your letter that you are attending the Connecticut State Medical Society Meeting.

PROGRAM

The House of Delegates will be held on May 10th and the scientific program will be concentrated in one day, May 11th. The general program will be held in the ballroom between 10:30 A.M. and 12:30 P.M. and the section meetings will be held in the morning and afternoon in the rooms listed in the program.

PRESIDENT'S INAUGURATION

The inauguration of the new President will take place at the House of Delegates meeting on May 10th, at about 3:00 P.M. All members are invited to attend the inauguration. A reception for the President will be held immediately following the close of the meeting.

EXHIBITS

All the exhibits will be located in one section of the ballroom. Physicians should take advantage of the opportunity to review what is new and timely by visiting the commercial exhibits.

ALL ACTIVITIES WILL TAKE PLACE AT THE
RAMADA INN UNLESS OTHERWISE INDICATED

**HOSPITAL RESIDENTS, INTERNS AND MEDICAL
STUDENTS ARE CORDIALLY INVITED TO ATTEND
THIS MEETING**

**ANNUAL MEETING OF THE
HOUSE OF DELEGATES**

**WEDNESDAY, MAY 10, 1989
BALLROOM**

Presiding:

Kenneth M. Robbins, M.D., *Middletown, Speaker of the House*
Sultan Ahamed, M.D., *Norwich, Vice Speaker of the House*

9:30 REGISTRATION OF DELEGATES

10:00 CALL TO ORDER

REPORTS OF OFFICERS, COMMITTEES, OTHERS
OLD AND NEW BUSINESS
REFERENCE COMMITTEE HEARINGS

12:00 GUEST SPEAKER

Jerald R. Schenken, M.D., Omaha, Nebraska, Member,
Board of Trustees, AMA

1:00 LUNCHEON

2:00 CALL TO ORDER

PRESENTATION AND AWARDS
REPORT OF THE CSMS AUXILIARY
ADDRESS OF THE PRESIDENT
Norman A. Zlotsky, M.D., Rockville
ELECTION OF OFFICERS AND COMMITTEES
INAUGURATION OF NEW PRESIDENT
Roger S. Beck, M.D., Hartford
INAUGURAL ADDRESS
AWARD TO PAST PRESIDENT
REFERENCE COMMITTEE REPORTS
INTRODUCTION OF GUESTS
RECEPTION TO FOLLOW

**GENERAL SCIENTIFIC PROGRAM
THURSDAY, MAY 11, 1989
MORNING SESSION**

8:15 REGISTRATION—LOBBY

**8:30-10:00 MEETINGS OF THE SECTIONS OF THE
SOCIETY**

(Listing elsewhere in program)

BALLROOM

10:20 CALL TO ORDER AND WELCOMING REMARKS
ROGER S. BECK, M.D., HARTFORD
President, Connecticut State Medical Society

Presiding

James D. Kenney, M.D., *New Haven*, Chairman of the Com-
mittee on the Program of the Scientific Assembly

**10:30 THE PRESENT DAY PRACTICE OF ORGAN
TRANSPLANTATION; AN OVERVIEW OF BIO-
LOGY AND TECHNOLOGY**

WILLIAM H. MARKS, M.D., PhD., NEW HAVEN;
Associate Professor of Surgery (Transplantation), Yale
University School of Medicine

11:15 DISCUSSION

**11:30 ORGAN TRANSPLANTATION; ETHICAL AND
SOCIAL ISSUES:**

ROBERT J. LEVINE, M.D., NEW HAVEN; Pro-
fessor of Medicine and Chairman of the Human Investi-
gation Committee, Yale University School of Medicine

12:15 DISCUSSION

12:30 INTERMISSION TO VISIT EXHIBITS

1:00 LUNCHEON

**THURSDAY, MAY 11
MEETINGS OF THE SECTIONS OF THE SOCIETY
MORNING SECTION PROGRAMS**

**SECTION ON DERMATOLOGY
AND DERMATOLOGIC SURGERY**

8:30

Jericho Room

President: Jeffrey N. Alter, M.D., Waterbury
Secretary: Robert D. Greenberg, M.D., Vernon

**LASERS IN DERMATOLOGY:
BOON OR BOONDOGGLE**

GARY J. BRAUNER, M.D., NEW YORK; Associate
Clinical Professor of Dermatology, New York Medical
College, Valhalla, New York

SECTION ON FAMILY PRACTICE

8:30 A.M.

Arlington Room

President: Karl R. Friedmann, Old Lyme
Secretary: Nelson C. Walker, II, M.D., Storrs

**GENERAL DISCUSSION OF SOCIO-ECONOMIC
AND MEDICAL ISSUES FACING FAMILY PRAC-
TICE**

CONTINENTAL BREAKFAST WILL BE SERVED

SECTION ON INTERNAL MEDICINE

8:30 A.M.

Brunswick Room

President: Brett J. Gerstenhaber, M.D., New Haven
Secretary: Andrew C. Wormser, M.D., New Haven

**8:30 PULMONARY EMBOLI: STATE OF THE ART IN
DIAGNOSIS AND TREATMENT**

MATTHEW A. MILLER, M.D., DANBURY; Asso-
ciate Clinical Professor of Medicine, Yale University
School of Medicine

**9:15 INFECTIOUS DISEASE: WHAT'S NEW IN THE
FLUORINATED QUINOLONES?**

GEORGE F. THORNTON, M.D., WATERBURY;
Clinical Professor of Medicine, Yale University School
of Medicine and UConn School of Medicine

10:00 DISCUSSION

SECTION ON NEUROLOGY

9:00

Ivoryton Room

President: Jan H. Mashman, M.D., Danbury
Secretary: Arthur M. Seigel, M.D., New Haven

IATROGENIC NEURO MUSCULAR DISORDERS

KESHAV R. RAO, M.D., FARMINGTON; Assistant
Professor of Neurology, Department of Neurology, Uni-
versity of Connecticut School of Medicine

**SECTION ON PHYSICAL MEDICINE
AND REHABILITATION**

8:30 A.M.

Fairfield Room

President: John W. O'Brien, M.D., New Haven
Secretary: Mary Ita Malone, M.D., Middletown

THE CUTTING EDGE OF BIOFEEDBACK

JOHN GIANUTSOS, PH.D., NEW YORK; Rusk In-
stitute of Rehabilitation, New York University School
of Medicine

AFTERNOON SECTION PROGRAMS

SECTION ON ANESTHESIA

- 4:00 P.M.** **Regency Room**
President: Jonathan D. Katz, M.D., Bridgeport
Secretary: Vacancy
- 4:00 UPDATING IN PEDIATRIC ANESTHESIOLOGY**
RYAN COOK, M.D., PITTSBURGH; Professor of Anesthesiology, Children's Hospital of Pittsburgh
- 7:00 DINNER—ROYAL ROOM**

SECTION ON ALLERGY

- 6:30** **Renaissance Room**
President: Anthony V. Piccirillo, M.D., Wallingford
Secretary: Jeffrey D. Miller, M.D., Danbury
- DINNER**
GUEST SPEAKER: JOSEPH S. MCGUIRE, M.D., NEW HAVEN; Professor of Dermatology, Yale University School of Medicine
- TOPIC: ECZEMA UPDATE

SECTION ON NEUROSURGERY

- 2:30** **Jericho Room**
President: John N. German, M.D., New London
Secretary: Isaac Goodrich, M.D., New Haven
- NEUROSURGICAL DISCUSSION**
WILLIAM F. COLLINS, M.D., NEW HAVEN; Professor of Neurosurgery and Chief of Surgery, Yale University School of Medicine

SECTION ON OBSTETRICS AND GYNECOLOGY

- 3:30** **Arlington Room**
President: Samuel G. Smith, M.D., Manchester
Secretary: Stanley R. Lavietes, M.D., New Haven
- 3:30 AFTER TORT REFORM: THEN WHAT?**
KENNETH V. HELAND, J.D., WASHINGTON, D.C.; Associate Director, Department of Professional Liability, American College of Obstetricians and Gynecologists
- 4:30 RECEPTION — POOLSIDE**

SECTION ON PATHOLOGY

- 2:30** **Danbury Room**
President: Dennis G. O'Neill, M.D., Manchester
Secretary: Irwin Nash, M.D., New Haven
- ESTROGEN RECEPTOR ASSAY FOR USE IN PARAFIN-EMBEDDED TISSUE**
DAVID C. WILBUR, M.D., FARMINGTON; Associate Pathologist, UConn Health Center

SECTION ON COLON AND RECTAL SURGERY

- 2:30** **Fairfield Room**
President: Steven A. Hirshorn, M.D., Bridgeport
Secretary: Charles E. Littlejohn, M.D., Stamford
- CRYOHEMORRHOIDECTOMY REVISITED**
STEVEN A. HIRSHORN, M.D., BRIDGEPORT; St. Vincent's Medical Center Bridgeport

SECTION ON UROLOGY

- 2:30 P.M.** **Guilford Room**
President: James F. Walsh III, M.D., Bridgeport
Secretary: Haik K. Kavookjian, M.D., Stamford
- BUSINESS MEETING**

SPECIAL NOTICES

CONTINUING MEDICAL EDUCATION CREDITS

AMA PHYSICIANS RECOGNITION AWARD

As an organization accredited for continuing medical education by the Affiliation Committee for Continuing Medical Education, Yale University School of Medicine certifies that this program is acceptable for Category I credit as specified by the American Medical Association for the Physicians Recognition Award. Credit is granted in this category on an hour for hour basis.

AMERICAN ACADEMY OF FAMILY PHYSICIANS

The Commission on Education of the AAFP has accredited the scientific program of the Society's Annual Meeting for two hours of prescribed credit for the general lecture and one and one half hours of elective credit for each lecture attended which is presented by the individual specialty sections of the Society.

IMPORTANT — PLEASE NOTE

The following section of the Society will not be meeting on May 11. Following is the date and location of the meeting:

SECTION ON ORTHOPEDICS

MAY 18, 1989

- 4:00** **Ramada Inn, Meriden**
President: Malcolm S. Edgar, Jr., M.D., Norwich
Secretary: Gerard J. Lawrence, M.D., Willimantic
- RELATIONSHIP BETWEEN THE ACADEMY AND THE FEDERAL GOVERNMENT**
NICHOLAS G. CAVAROCCHI, WASHINGTON, D.C., Director, Washington Office of American Academy of Orthopedic Surgeons

TECHNICAL EXHIBITS

Our exhibits contribute to the value of our assembly by presenting goods and services of interest and importance to physicians. Personal visits to the booths will increase your understanding of the materials and programs on display.

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Blue Cross-Blue Shield of Connecticut, North Haven, Connecticut
Brentwood Instruments Incorporated, Torrance, California
Connecticut Medical Insurance Company, (CMIC), North Haven, Connecticut
Dodson Insurance Group, Kansas City, Missouri
Eli Lilly & Company, Indianapolis, Indiana
Forty-Seven Medical Equipment Corporation, New York, New York
Gaylord Hospital, Wallingford, Connecticut
Merck & Company, West Point, Pennsylvania
Safeway Disposal System Incorporated, Middletown, Connecticut
Travelers Insurance Company, Wallingford, Connecticut
Wertheim Eilers Associates, Incorporated, Hartford, Connecticut

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The Boehringer-Mannheim Diagnostic Company will provide free cholesterol screening on the Reflotron machine in the exhibit hall.

The Connecticut State Medical Society acknowledges with thanks an educational program grant received from:

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The President's Page

RBRVS: Continued



As promised earlier, this President's Page will highlight the Resource Based Relative Value Scale activity in the past three months. The extraordinary outcome of the debate at the AMA's Semi-Annual Meeting was the unity shown by all groups involved. While a significant list of modifications was recognized as necessary, the diverse specialty groups still looked to the AMA as medicine's voice in this endeavor, though all may provide input where needed.

In the meantime, the Physician Payment Review Commission (PPRC) has begun its hearings in preparation for reporting to Congress its recommendations for financing Medicare. The Commission members recognize that they must control volume to be effective, something which the RBRVS *per se* does not do.

One direction is to develop parameters for appropriate care and not to pay for inappropriate care. Many groups, including the PPRC, the Prospective Payment Assessment Commission and specialty societies, are working in this area. Some central body with Solomonic intelligence will be needed to turn such information into a volume control, while recognizing that medical care is a continually evolving process, that regional differences are possible with similar percentages of good outcomes, and that quality could be hurt by too rigid an interpretation of such parameters without due process review by physician peers. In other words, the whole process is becoming more and more complicated, as expected.

RBRVS problems are seen in the variations in coding practices: for example, whether a surgical procedure is bundled into a global code or broken down into pre- and postoperative segments as well as individual parts of the procedure. No handle on costs will be possible until such a global fee can be developed not only for surgical procedures but also, for example, for what constitutes a periodic check-up for a 70-year-old patient.

Other volume controls that PPRC is looking at are expenditure controls for physicians. Such controls would be based on data showing the growth and aging of the elderly population, changes in prices of services, and service utilization in an area. Fee updates would depend on whether expenditures for an area stayed within the targeted range. Detailed policy has not yet been developed as recommended, but the PPRC may attempt with expenditure targets to make physicians more responsible for appropriate use of services and for decreasing the government's role in the process. This coincides with the ideas of Dr. Roper, Administrator of the Health Care Financing Administration (HCFA), who would like to capitate Medicare on a regional basis by providing a specific lump sum for all medical services.

With all this actually going on, there are no answers now on what medical reimbursement will ultimately look like. PPRC expects 1991 to be the earliest possible date for implementation of a modified resource based fee schedule. Our AMA delegates are very much aware of your interest as they monitor the deliberations. Appropriate action items will be brought to the CSMS Council and House of Delegates as they arise, and we will look to those who have special interest and expertise to help us provide input to the AMA.

Norman A. Zlotsky, M.D.
President



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Reflections on Medicine

Telling the Tall Tales

ROBERT U. MASSEY, M.D.

The Guns of August was the first of Barbara Tuchman's books that I read. For our generation the Great War had been our fathers' war, and we had grown up with the memory of it; *our* war was yet to come. The movies we liked, the patriotic songs, many popular stories, novels, and much of the poetry had the flavor of 1914-18. When we came to learn something of the official history from our high school textbooks, just before the last chapter on the 1928 election and the Depression, we added little to the words we already knew: Sarajevo, the Somme, the Lusitania, Pershing, the Kaiser, and Woodrow Wilson and the League of Nations, a few names and places to associate with the old twice-told tales. It took the skillful storytelling of Barbara Tuchman to make us feel that we, 30 years later in 1962, now understood the *real* history of that war.

Historians said she did not always get it quite right, but we paid little attention to them. More books followed and we did not stop reading Barbara Tuchman even after we heard that she had not earned a professional degree in history, and during the past few months we hoped that *The First Salute* would not be her last book, but it turned out to be just that. Now we shall need another good amateur historian with a talent for wordcraft, just as the theologians have needed the great preachers and the scientists have needed the good science writers. If scholars are to write only for other scholars, and they must, and yet not have their interpreters, then the rest of us are left to ignorance and folly, understanding, as we do, only the vernacular, the blind leading the blind.

Recently I was displaying my amateur knowledge of the origins of the alphabet by drawing an upside-down *A* and showing that it had begun as a picture of a cow's head, called *aleph* in Hebrew, and probably something like that in Phoenician, and then a *B*, two rooms in a house, *beth*, with examples that others would recall, Beth Israel, Bethlehem, Beth El. A professional linguistic scholar in the crowd let me down by explaining patiently that recent studies had clearly shown that this was much too simplistic an explanation, probably dead wrong. I

bided my time, waiting to nail him when he started to talk about medicine, which he was sure to do, and I did; between the two of us we chilled all conversation in the group to nothing more serious than the Red Sox. All of this should be a challenge, but for most of us there is just not enough time; first-rate scholarship is inaccessible to any but other specialists in the field, and if there are no translators, no amateurs to tell the tale, *Biblia Sacra* must remain a closed book, and those without Latin, yet curious about the two creation stories in Genesis, finally give up and switch on the ball game.

The analogy can go too far, but the transcribers should themselves be amateur scholars in the discipline, not only masters of irregular Greek verbs; a good novelist who is not a decent historian may write a best-selling history, but it will be bad history, possibly dangerous. Scholarly findings can be written in "a language understood of the people," even simplified, without being simplistic or wrong. The immune system can be successfully explained to a ten-year-old without distorting a single fact, omitting only a tedious philosophic discussion of what a *fact* is. The wonder of the periodic table can be told in such a way as to elicit an "ah ha!" from a 16-year-old who will never look inside a molecule or even a chemistry laboratory. William Harvey's "discovery" of the circulation can engage the attention of a mixed crowd of seniors for an hour without the speaker ever compromising historical or biographical truth. And the great thing is, they will remember most of these things a year later, or recall them when they see or hear of them again.

We may never quite bridge the chasm between the two cultures, much less bring serious disciplines together; violinists cannot understand horn players, and immunologists are no good when it comes to working out visual pathways, so why should we expect legal scholars to see the world as scientists do? But the specialists and scholars do need to communicate with the rest of us, or they need to make room for those who can. Barbara Tuchman was one who could manage the historians and all their works, and bring her strong subjectivity to match their cool objectivity, unafraid to write of human passion, folly, and goodness from her point of view, which she took to be ours as well. We shall miss her spirited telling of the tall tales of our history.

ROBERT U. MASSEY, M.D., Professor, Division of Humanistic Studies in Medicine, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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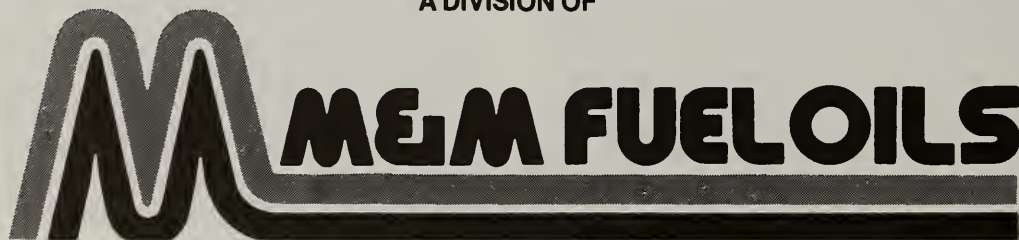
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Winter Reading: Legal Regulation of the Health Care System

JOSEPH M. HEALEY, J.D.

Now that the Connecticut Supreme Court has handed down its decision in the *McConnell*¹ case, it is tempting to leave incomplete the two-part series begun last month dealing with two recent health law texts. In its unanimous decision, the Court affirmed the right of Ms. McConnell's family to implement her right to refuse artificial nutrition and hydration. The majority of the Court found such an outcome consistent with the meaning and intent of the Connecticut "Death with Dignity" Statute. In a concurring opinion, one justice agreed with the result, but articulated his own basis rooted in a common law right to self-determination. Since full discussion of the *McConnell* case is likely to take more than one column, I have decided that it would be less disruptive to proceed with the second part of the series this month and to take up the *McConnell* case next month. In this way, both topics can receive appropriate attention.

Last month's column and this month's column have been designed to introduce two recent health law texts and to encourage your examination of them. This month the focus is on Clark C. Havighurst, who is the William Neal Reynolds Professor of Law at Duke University. His volume *Health Care Law and Policy: Readings, Notes, and Questions*² has been published by Foundation Press as part of its University Casebook Series. This is an impressive work of almost thirteen hundred pages which contains a broad range of primary and secondary sources in health law. Emphasizing his longstanding interest in regulation of the health care industry, Professor Havighurst has divided his work into four parts, addressing

many of the most prominent issues of this aspect of health law: the tensions of health policy; the mechanisms of quality assurance; controlling health care costs, and cross-cutting issues involving ethics, law, and economics. Among the many subtopics considered in these sections are: the distinctive problems of regulating health care; entitlements and obligations with respect to health care access; the tension between professionalism and commercialism in health care; antitrust concerns; quality issues arising out of individual and institutional credentialing; liability for adverse medical outcomes; controlling health care costs; and a closing section addressing the impact of catastrophic diseases such as AIDS on the health care system. In this volume, Havighurst has assembled a comprehensive collection of excerpts from medical, legal, ethical, and economic sources and has provided his own extremely worthwhile commentary in the form of notes and questions. While its length and its purpose as a textbook may deter the casual reader, this is such an extremely valuable book for those interested in understanding the historical foundation and contemporary application of those aspects of health law involving legal regulation of the health care process. Those who overcome the natural reluctance to tackle such an imposing volume will be very well rewarded.

REFERENCES

1. *McConnell v. Beverly Enterprises-Connecticut, Inc.*, 209 Conn. 692 (1989).
2. Havighurst CC: *Health Care Law and Policy: Readings, Notes, and Questions*. Westbury, New York, The Foundation Press, Inc., 1988.

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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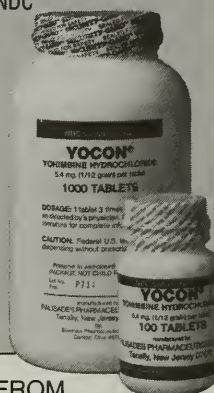
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References:

1. A. Morales et al., New England Journal of Medicine: 1221, November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

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Letter to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

IN FAVOR OF BILL 413: HELMET LAW

To the Editor: Victims of motorcycle injuries constitute a significant portion of the trauma center's patient population. The risk of death is 14 times higher than from an automobile accident.

From January 1986 to June 1987, our Trauma Unit admitted 48 motorcycle victims; 81% were male, 65% were Caucasian and 85% were single. 58% of these patients were unemployed and 25% had a detectable drug on board. Ninety percent of these victims were not wearing a helmet.

According to statistics printed in the Rockville, Connecticut, *Journal Inquirer*, there were 482 people killed on our highways in 1988. Five percent of these deaths were motorcycle drivers. In our Trauma Unit, 70% of deaths from motor vehicle accidents occur as a result of head injuries; for deaths related to motorcycle accidents, the percentage is higher.

In a study conducted by of the American Journal of Surgery, "Patterns of Injury in Helmeted and Non-Helmeted Motorcyclists," accident records were reviewed from 1 January 1983 through 31 May 1987. There were 367 accidents involving motorcycles. Of the injured motorcyclists, 64% were nonhelmeted and 36% were helmeted. There were 23 deaths in the nonhelmeted motorcyclists and seven in the helmeted. Fifty percent of the nonhelmeted motorcyclists sustained brain injuries compared to 25% of the helmeted patients.

The injury patterns for motorcyclists versus moped drivers are quite similar. However, there tend to be more head injuries with moped drivers simply because they notoriously use helmets less frequently.

The ultimate tragedy of these injuries, particularly head injuries, is that they effect groups whose mean age is from 25 to 29.9. Twenty-five percent of the impairments that these people suffer are irreversible. The remaining 75% involve at least some element of reversibility, but for the severely brain injured, the care is often chronic, lasting years. The emotional impact on the victim and the victim's family is extraordinarily devastating. Words do not sufficiently explain the enormous price which is paid by all involved because of one single tragic event.

Compounding this tragedy is the cost to the public. The Harborview Medical Center in Seattle conducted a study, published in the *Journal of the American Medical Association*, in which 105 patients were evaluated in terms of cost. The mean time span for treatment was 20 months, costing more than 2.7 million dollars, with an average of \$25,764 per patient. The majority (63.4%) of care was paid for by public funds, with Medicaid accounting for more than half of all charges.

In the *Journal of Trauma* 1986, the Massachusetts General Hospital published data on 47 hospitalized motorcyclists from 1 July 1982 to 1 July 1983. The average cost was \$15,114 (not including rehabilitation costs). The authors also point out that 46% of the patients had no medical insurance.

A composite of recommendations from the *Journal of the American Medical Association* and the *Journal of Trauma* is as follows:

1. Helmet Law is recommended.
2. In an era where social and economic accountability plays an increasingly important role, motorcyclists should provide themselves with medical and disability insurance.

My own recommendation is that Bill 413 be enacted: that the law mandate helmet use and that operators of motorcycles be adequately insured or risk penalty by law.

What is most important is life and quality of life. We have an obligation to protect our species by whatever methods necessary. We also have an obligation to avoid burdening the public and public funds. Society must begin to take responsibility for its actions and the impact these actions may have on other segments of the population.

Anthony S. Morgan, M.D.
Director, Trauma Services

St. Francis Hospital and Medical Center
Hartford, CT

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BOOK REVIEW

Setting Limits: Medical Goals in an Aging Society

By Daniel Callahan, New York, NY, Simon and Schuster, 1987. 256 pp. \$18.95

Setting Limits is a book about the rapid aging of the U.S. population, the potential consequences of this phenomenon for both young and old, and appropriate societal responses. Subtitled "Medical Goals in an Aging Society," Callahan's work is public policy analysis on a grand scale, drawing upon historical, sociological, and ethical perspectives to examine the problem of aging in contemporary society, reciprocal obligations between the generations, and viable strategies for addressing the health care needs of the country's growing number of elderly. His central conclusion, that the elderly should be excluded from life sustaining medical care, is likely to prove disturbing to the elderly, the medical community, and, indeed, to most Americans.

At the heart of Callahan's analysis are two complementary concerns. The first is that, despite continued improvements in the life expectancy, health status, and economic well-being of the elderly (which have, in turn, led to expanded social roles for many older persons), old age has, in contemporary society, been stripped of its personal meaning and social significance. Callahan holds modern medicine largely, though not exclusively, accountable for the decline of old age as a valued and meaningful period in one's life. By constantly pushing back the limits of a "natural life span" through the development of life-extending technology, medical science has distracted us from the ultimate ends we all face: physical decline, disability, and death. In old age, the illusion that life can be indefinitely, if artificially prolonged leads the elderly to a preoccupation with "today" rather than to a more socially appropriate and personally fulfilling contemplation of their lives, their impending deaths, and what they will leave behind them for future generations.

Callahan's second, related concern is with the escalating economic and social costs of indefinitely prolonging the lives of the elderly. Again, medical science has, in the author's view, played a central role in expanding these costs. Together with more effective public health measures, a better standard of living, and improvements in personal health behavior, medical advances have virtually ensured survival of the elderly despite the inevitable diseases and disabilities of old age. The result has been a steady increase in the number and proportion of older persons requiring medical care and related social services. Further, medical technologies under development are targeted largely to curing the diseases and infirmities of old age, thereby ensuring that the per person costs of caring for the elderly will be even greater in the future. In the case of the elderly, such costs, according to Callahan, know no limit. "Unlike those of younger age groups, the needs of the elderly for continuing good health are of

their very nature open-ended: in old age, the conquest of one disease only guarantees death from some other disease, one which, if conquered, will give way to some further lethal condition." Continued attempts to address the open-ended health care needs of the elderly can only bankrupt the current system and compromise its ability to meet the needs of future generations.

The author offers a two-fold strategy for addressing these concerns. Initially, the personal and social meanings of old age must be restructured in such a way that they do not depend on continued survival at any cost. Second, the goals of medical care for the elderly must be accordingly readjusted.

In the first instance, Callahan advocates a "rediscovery" of the "life cycle" concept, characterized by relatively fixed stages, an inevitable period of decline at the end of life, and death as an "absolute limit." Recognition and acceptance of the reality of the life cycle will, according to Callahan, facilitate the elderly's understanding and acceptance of aging and death, and resensitize them to the value of both past and present. As a result, they will again be in a position to share with younger generations the special insights unique to old age. While the gifts of time and money that the elderly often bestow on their children and grandchildren may readily be done without or supplied by others, "Only the aged can provide a perspective the young need if they are properly to envision their own lives: that of the cycle of the generations and its import for the living of a life." In Callahan's words, "It should be the special role of the elderly to be the moral conservators of that which has been and the most active proponents of that which will be after they are no longer here." Such a role would not only be a fulfilling one for the elderly, but would generate "what ... ought to be the *primary* aspiration of the old, which is to serve the young and the future."

In the second instance, medicine's passion for expensive high technology means of prolonging life must be bridled and health care resources redirected to appropriate *care* of the elderly and to ameliorating of the causes of *premature* death. In Callahan's terms, a premature death is one which cuts short the "natural life span." That is, it is a death which occurs before, "... one's life possibilities have on the whole been accomplished," and, "... one's moral obligations to those for whom one has had responsibility have been discharged." While rarely welcomed, death after this point in the life cycle is, he believes, generally seen as fitting or at least acceptable. For most of us, he argues, the natural life span will be accomplished by our late 70s or early 80s.

For Callahan, these concepts must be more than guiding principles. In the interests of fairness, and to be effective in containing health care expenditures, they must be embodied in a uniform public policy. Under such a policy, the government would maintain a responsibility to assist people in living out a natural life span, "...but not actively to help extend life medically beyond

that point.” By life-extending treatment, Callahan means, “...any medical intervention, technology, procedure, or medication whose ordinary effect is to forestall the moment of death, whether or not the treatment affects the underlying life-threatening disease or biological process.” In short, the government would be, “obliged to develop, employ, and pay for only the kind and degree of life-extending technology necessary for medicine to achieve and serve the end of a natural life span.” Beyond that point, government would, “...provide only the means necessary for the relief of suffering, not life-extending technology.”

In supporting his position, Callahan’s self-assigned tasks are to demonstrate that the rationing of health care has become imperative, that to base such rationing on age rather than “need” is morally defensible, and that his proposals are pragmatically workable. To these ends, he provides a detailed documentation of the elderly’s contribution to mushrooming health care expenditures in the U.S., a painstakingly thorough analysis of our personal and societal obligations to the elderly (and their obligations to society), and a set of practical guidelines for making individual treatment decisions under his proposed framework.

Overall, these presentations are thoughtful and scholarly. Callahan is particularly effective at anticipating, though rarely at refuting, criticisms of his proposals: that, for example, there are less worthy public expenditures that could be targeted for cost containment than health care for the elderly, that new ways of organizing and financing health care for the aged may yet be found to achieve what cost reductions are necessary, that determining the end of a patient’s “natural life span” will be difficult if not impossible, or that the application of life-extending technology at any age raises the possibility of open-ended health care costs. Too often, Callahan voices but summarily dismisses such criticisms.

In the end, however, it is the overall thrust and tone of the author’s analysis which is likely to trouble professional and lay readers alike, perhaps because they run, or appear to run, counter to our everyday perceptions of reality and to our deeply held values. At the simplest level, it will come as a surprise to many if not most readers over the age of 80 to find that their remaining years have been stripped of meaning, whatever their health or social circumstances. Similarly, while Callahan disavows any attempt to diminish the value of the aged or old age, his frequent admonishment to the elderly that, in their “subsidized retirement,” they should “redeem” old age by accepting their physical decline with grace and self-sacrifice in the interest of the young seems to suggest that today’s aged are somehow more prone than those of the past to self-indulgent consumerism at the expense of their children and grandchildren: a view unlikely to be held by most elderly or their families, or supported by scholarly research. Nor are readers likely to

find a sense of fairness and intergenerational equity in a system that would deny life-sustaining treatment to an otherwise healthy person solely on the basis of advanced age, particularly when such an injunction would apply only to those relying on government assisted care.

These limitations should not detract potential readers from their own careful examination and consideration of Callahan’s thesis. In *Setting Limits*, Daniel Callahan has put forth an unquestionably bold and articulate challenge to contemporary medicine, to our health care system, and to the nation: do better in meeting the health care needs of our elderly within our existing system of care or prepare for widesweeping changes very much at odds with the traditional precepts of medicine.

Richard A. Lusky, Ph.D.
Director, Gerontology Studies Unit
University of Connecticut Health Center
Farmington, CT

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From the Executive Director's Office

CALL

ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1989 Annual Meeting of the House of Delegates will be held at the Ramada Inn, 275 Research Parkway, Meriden. The meeting will commence at 10:00 A.M. on Wednesday, May 10, and will continue until all business has been concluded.

9:30 Registration and Continental Breakfast

10:00 Call to Order

Norman A. Zlotsky, M.D., President

Kenneth M. Robbins, M.D., Speaker of the House

Katherine C. Ill, M.D., Secretary

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides that:

Resolutions may be introduced by any Active, Life Member, Student Member or Postgraduate Physician Member of The Society, in compliance with the following provisions.

- a. *All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.*
- b. *Component county associations or the Student Member or Postgraduate Physician Member Associations whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc., be considered regular business if they are received later than fifteen days prior to the date of the meeting.*
- c. *Reports, recommendations, resolutions or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered as regular business.*
- d. *Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for consideration by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provisions of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.*

COUNCIL MEETING

Thursday, February 23, 1989

Attendance

Present in addition to the Chairman Dr. Joseph C. Czarsty were Drs. Ahamed, Beck, Bobruff, Bonner, Catrini, Eslami, Fox, Freedman, Hollister, Jr., Ill, Kamens, Kaufmann, McDonnell, Orphanos, Petrie, Reyelt, Jr., Robbins, Rubin, Sosa, Van Syckle, Villa, Welch, Zanker, Zeppieri and Zlotsky.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Sullivan, Dr. James, Mr. Tomat (FCMA), and Mr. Coffey (HCMA).

Absent were: Drs. Blum, Chmielewski, Dardick, Lesnik, O'Brien, Rose, Sadowski, Schwartz, Upham and Wetstone.

Physicians Serving on State and Federal Agencies

Dr. Kamens, Medical Director of CPRO, reported that CPRO has had its contract renewed effective April 1, 1989 and it is called the "third scope of work." There have been some significant changes which again include precertification of some procedures. The federal govern-

ment has devised a specific methodology for quality of care issues and assigned points to these issues. The CPRO will keep hospitals informed of the various changes being undertaken.

Dr. Kamens also discussed a report that had appeared in the *New York Times* concerning deaths occurring due to drug reaction among the elderly, reportedly caused by misdiagnosis, lack of emphasis on geriatric training, faulty prescription writing and patient misuse. He suggested that perhaps CSMS would wish to make a pilot study of these allegations. Following discussion, it was VOTED that the Chairman of the Council appoint a small committee of councilors and staff, along with Dr. Kamens, to investigate the potential to implement a program of study such as outlined and report back to the Council.

Report to the President

Dr. Zlotsky reported on the following items:

Legislation—He appeared at a hearing on the use and abuse of steroids in athletes and an attempt will be made to make steroids a controlled substance. Dr. David Thompson of New London presented excellent testi-

mony at a hearing on triplicate prescription; however, the outcome on this legislation is unpredictable. Medicare Assignment has been killed in two committees and the only way it can resurface is as an amendment to another bill, and this will have to be monitored carefully. The Nurse Prescription Bill, which was written by an attorney from the Health Department was reviewed by Drs. Zlotsky and Beck and several changes were made in the bill, although some items remain in the bill which are not entirely satisfactory. Dr. Zlotsky called on Dr. Zanker to discuss the issue of budget cuts in the funding of nursing homes by the Department of Income Maintenance. The issue will be studied by the CSMS Legislative Committee.

Legislative Fitness Day—A legislative fitness day is being co-sponsored with the Governor's Fitness Committee on March 15th at the state capitol. Members of the CSMS Committee on Sportsmed will be on hand to take the various tests and brochures will also be available. Any expense for this program is being underwritten by COMPAC.

Tort Reform—Attorney Donald Elliot, who researched the constitutionality of establishing a cap on non-economic damages, is currently preparing model legislation which it is felt would have the best chance of being held constitutional in Connecticut.

CMMI—At the present time, the bylaws committee did not meet to discuss the possibility of providing for specific members to be seated on the CMIC Board. Dr. Eslami assured the Council that this issue would be discussed when the bylaw committee meets, and that the interest of CSMS in CMIC would be protected.

Report of the Executive Director

Tim Norbeck reported on the following items:

Malpractice Insurance—A letter was distributed to the Council members from the St. Paul Insurance Company responding to the release by the Minnesota Commerce Department on their "Malpractice Claim Study, 1982-87" and subsequent nationwide "Nightline" program which asserted that inflated loss reserves were driving unnecessary premium increases. St. Paul engaged their own actuarial firm to review the report and the findings were that the report used unsound procedures and inappropriate data in evaluating reserve adequacy and rate levels and the conclusions were incorrect.

AMA Nominations—Dr. Petrie is campaign manager for Dr. Kamens who is running for a slot on the Council on Medical Service and Dr. Freedman is campaign manager for Dr. Yapp, who is seeking the resident slot on the AMA Board of Trustees. Promotional material has been developed for both campaigns and will be mailed to members of the AMA House of Delegates.

Ad Hoc Committee on Membership

Dr. Freedman reported that the committee is making an ongoing effort to increase CSMS membership and requested that counties and individual physicians assist

in this program by enlisting new members. He reported that two large counties have large numbers of physicians who belong to the county only and not the state. Every effort will be made to have these two counties discontinue the practice of county members only and it was suggested that if this trend could not be stopped, that CSMS should consider allowing State Society members only in those counties that allow county membership only.

Update M.D. Health Plan

Dr. Van Syckle reported on the progress being made between the recent stock offering and the new physician enrollment program. Approximately 250 additional physicians have joined the program bringing the total up to 2,000 physician participants. An appropriate network of physicians is being developed and with additional focused recruitment, the needs of the program will be met in the near future. At the present time there are over 12,000 members and the plan continues to grow. January was its first million dollar month.

Charitable Trust

Melinda Agsten, Attorney from Wiggin & Dana, joined the Council to review the actions to be taken to implement the Charitable Trust. The Council had previously approved the establishment of a Charitable Trust in March of 1988. Copies of the Trust Agreement were distributed with the agenda to all members of the Council. Following detailed discussion, it was VOTED to approve the documents submitted with the following amendments:

- a. Change references to "President of the Council" to "President of the Society."
- b. That the President of CSMS select the Trustees and submit to the Council for approval.
- c. That under the provision for removal of trustees, it be noted that advance notice be given by two-thirds of the trustees present and voting and that removal be with or without cause.
- d. Successors—When vacancy occurs for any reason, notice should be given immediately to the Council to name a successor.
- e. Terms should be limited to two terms of three years each and should be staggered.
- f. No compensation for trustees.
- f. Trustees cannot amend Trust without CSMS Council approval.

Connecticut Physician's Group Purchasing Plan, Inc.

At the House of Delegates on May 4, 1988, a resolution was approved "That the rights and powers of CSMS as a shareholder of Connecticut Physicians Group Purchasing Plan, Inc. shall be exercised by the Council of CSMS, and the Council is hereby authorized and empowered to act on behalf of CSMS with respect to all matters concerning CPGPP." It was VOTED to approve the Bylaws with the suggestions that an appropriate

name be given to the corporation. It was further VOTED to approve the resolution authorizing the President and/or Executive Director to take whatever actions necessary to establish the subsidiary in compliance with the Bylaws.

Public Information Program

Dr. Sosa had suggested that the Auxiliary study the feasibility of having store fronts on Main Streets in each county to serve as public information stations. Dr. Czarsty reported that Mrs. Reed, Auxiliary President, had informed him that the Auxiliary did not have the manpower to undertake such a proposal. Following discussion, it was suggested that county medical associations be encouraged to establish programs of public information on health related matters and also encourage careers in health, with the assistance of the Executive Director's office in planning programs. It was VOTED to refer this suggestion to the Committee on Public Affairs for study and implementation.

Ray Sullivan reported on the items that the Committee on Public Affairs is currently undertaking, i.e., TV programs, participation in the Health Fair, where cholesterol screening will be done, pamphlets on economic and health related issues, press releases on current medical subjects and arranging interviews on radio talk shows.

Report of Subcommittee on Preliminary Study of Nominations

With a few amendments, it was VOTED to approve the report of the Subcommittee and to transmit the complete slate of nominees to the House of Delegates for election with Council recommendation for approval. It was further VOTED to increase the Committee on Physician Health to 15 members and to rename the Committee on Allied Medical Services to the Joint Practice Committee with the Connecticut Nurses Association. It was also VOTED that Dr. Zlotsky would chair a new Committee on Allied Medical Services and submit a list of nominees for the committee to the Council at the next meeting. The charges to the committees would be restructured accordingly.

Committee on Statewide Medical Planning

Several items were referred to the committee for study and following is the action taken on the various reports:

- a. *Section on Employed Physicians*—At the September 1988 Council meeting, it was voted to refer the concept of a Section on Employed Physicians to the Committee on Statewide Medical Planning for study. It was VOTED to approve the recommendation of the committee that a poll be undertaken of employed physicians to seek out their interests and that \$2,000 be allotted for this purpose. Dr. W. Raymond James, Chairman, who joined the Council to discuss the issue, stated that after studying the findings of the poll, the committee would make further recommendations to the Council.
- b. *Third Party Payors*—At the September 1988 Council meeting, the Committee on Statewide Medical

Planning was also charged to investigate feasible methods of preventing third party payors' intrusion into medical care. The committee reported that this issue has been of major concern for many years. The patients, or their employers, have long ago signed over their rights to privacy and to compensation without third-party interference and physician compensation has been a casualty. Affected parties should send letters of complaint to third party payors with copies to insurance company presidents, insurance commissioner, patient employer and appropriate attorneys. It was VOTED to accept the report as information.

- c. *Universal Health Planning*—At the January 1989 Council meeting a communication from Congressman Bruce Morrison's Medical Advisory Committee seeking a proposal from CSMS for the structure of universal healthcare insurance in Connecticut was referred to the committee for study. Dr. James reported that CSMS and AMA had recently completed participation in the formulation of the "Health Policy Agenda for the American People" involving over 425 representatives from 172 different health, health-related, business, government, and consumer groups who met over five years to confront the issues confronting the health sector into the next decade and the outcome of this broad consensus was published last year. Following discussion, it was VOTED that the Council forward the HPA recommendations 135 to 147, "Designing a Cost-Effective Payment System" and recommendations 148 to 161, "Defining the Role of the Government" to Mr. Freberg and the members of the Medical Advisory Committee, with an offer to refer them to physician experts in medical economics in Connecticut.

Committee on Insurance

At the Council's request, the Committee on Insurance conferred with disability insurance carriers to determine their attitudes toward payments to physicians who are HIV positive but do not have AIDS and who are not allowed to practice in a hospital because of possible contamination of patients. The committee met with representatives of the CSMS disability insurance coverage and received the following information from the two companies involved:

- a. AIDS would be considered a covered disability once the symptoms actually became physically disabling.
- b. No insurance carrier would commit right now to a ruling regarding a hypothetical situation, like the one suggested by the committee, until a test case is actually physically disabled, then she/he would be covered by the insurance. However, to be deemed totally disabled for the purpose of collecting disability insurance because of testing positive for HIV infection, but before any symptoms are manifested, is not likely, unless there is a court ruling that sets a legal precedent.

Resolution on Restraints Placed on Physicians by Claims Made Professional Liability Carriers

At the last Council meeting, the subject resolution, which was referred to the Council by the House of Delegates was referred to CMMI for study. The resolution was as follows:

“Resolved, That the CSMS Council investigate the possibility of having a reciprocal agreement among professional liability companies so that a physician may contemplate establishment of a medical practice in another state without the purchase of tail coverage, thus allowing the physician more mobility from one state to another. A reply has been received from CMIC indicating that this issue is one of national concern and being studied by the Physician Insurance Association of Amer-

ica and the AMA. The results of a study will be presented at a workshop in Boston on May 18-20, 1989 and a more definite response to the problem may be available at that time. It was VOTED to receive the communication as information.

Life Members

It was VOTED to receive the following list of Life Members as information:

William E. Hill, M.D., Naugatuck (NH)

David Luchs, M.D., Colebrook (L)

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on February 23, 1989. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

**DOCTOR-OWNED HMO TAKES OFF
MARCH PROGRESS REPORT**

M.D. HEALTH PLAN

M.D. Health Plan reached a significant plateau in January with monthly premium billings exceeding \$1,000,000. Enrollment has also been brisk. For the first quarter of 1989 (January, February, March), M.D. Health Plan's enrollment grew 65%, serving over 13,800 HMO members in 127 major employer groups. This represents 11,000 more members than at this time last year. Projected enrollment for the first quarter of 1989 was 12,000. As of March 21, M.D. Health Plan is 15% ahead of projection.

Additionally, in July, 1988, the Company diversified into innovative new products and services. The employer self-funded cost containment program MedCHOICE Health Care Network (MedCHOICE) has generated 5,000 new enrollees since July. The combined enrollment for M.D. Health Plan and MedCHOICE now exceeds 18,800 enrollees.

M.D. Health Plan made a \$53,000 profit in January and \$54,000 profit in February. The profit was a result of favorable medical cost experience and less than expected administrative cost. March's profit is expected to be higher as medical costs continue to trend lower than projection.

At this pace, M.D. Health Plan and MedCHOICE will generate \$12,000,000 in physician fees and 100,000 patients' visits to participating CSMS-IPA physicians in 1989.

By all industry standards, M.D. Health Plan and MedCHOICE are a success. Other Connecticut HMO's which began operations at roughly the same time, have less than half the number of enrollees.

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

FAMILY PRACTICE

Colchester—BC/BE Family Physician wanted to join busy solo Family Practice. Guaranteed income; good benefits; good coverage and no obstetrics. Potential for partnership in two years. Please send CV to: Dr. Kassem M. Khybery, 79 Norwich Ave., Colchester, CT 06415.

INTERNAL MEDICINE

BC/BE Internist to join three MD Internal Medicine Group in the New Haven area. Send CV to CSMS, c/o IM/NO.

Internist wanted as full-time Staff Physician for 568 bed multi-licensed, JCAH accredited geriatric institution and continuing care retirement community in Central Connecticut. Geriatric experience preferred. Will work standard workweek; rotation of evening and weekend call. Please send curriculum vitae with salary requirement to: CSMS, IM/HS. EOE.

Internist wanted to join existing division of three faculty geriatricians in academic setting to provide patient care for home care, nursing home, inpatient and outpatient evaluation programs, starting July 1989. Ongoing academic involvement including opportunities for teaching and/or research available, if desired. Competitive salary and benefits, no night or weekend call and four weeks vacation. For information contact: Fitzhugh C. Pannill, III, M.D., Chief, Division of Geriatrics, West Haven VA Medical Center, West Spring St., West Haven, CT 06516.

MISCELLANEOUS

Retired physician's fully-equipped office, including X-ray, available for immediate rental or sale. Excellent location. Please reply: Judith Turetsky, 496 West McKinley Ave., Bridgeport, CT 06604. (203) 367-9300 for further information.

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Gastroenterology. July '89. Age 28. Nat'l bds. AB elig. MD, Mount Sinai School of Medicine, NY, NY; Int. and Res., Long Island Jewish Medical Center, New Hyde Park, NY; Fellowship, Booth Memorial Medical Center, Flushing, NY. Prefers solo, group or associate type practice. Write, Jeffrey T. Dreznick, M.D., 63-53 Haring St., Apt. 608, Rego Park, NY 11374.

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Around the State

A course titled "A Real Return on Your Investment: The Educated Patient," will be held on 29 June 1989 at the University of Connecticut Health Center. The theme will be patient education and the role of physicians, nurses, pharmacists, and others in the health care team in making patients aware of cardiovascular risk factors. For more information, call Cecile J. Volpi, 679-3340.

Israeli-American Neonatology Symposium Set for June '89. The first Israeli-American Neonatology symposium will take place in Jerusalem from 29 June to 9 July 1989 under the co-sponsorship of Norwalk Hospital's Department of Pediatrics. Coordinator of the undertaking is **Peter S. Czuczka, M.D.**, of Westport.

The symposium will provide an opportunity for the exchange of ideas on neonatal topics between prominent physicians of both countries. **Ian Gross, M.D.**, chief of neonatology, and **Joseph Warshaw, M.D.**, chairman, department of pediatrics, both of the Yale Medical School, will be lecturers.

The Second Annual Conference on Lyme disease will be held on Wednesday, 7 June 1989 at Yale Medical School. This year's topics include:

- The ecology of Lyme disease including protective measures.
- Lyme disease in veterinary medicine.
- Animal models of Lyme disease and what they teach us about the disease in humans.
- The management of tick bites and treatment of Lyme disease in pregnancy.
- Work in progress regarding vaccine development.
- Controversies regarding optimal antibiotic therapy for all stages of Lyme disease.
- Late neurologic sequelae of *Borrelia burgdorferi* infection.

Roche Laboratories will help to support this program.

George B. Longstreth, M.D., a Fairfield general surgeon, produced the Health '88 Seminar for the Fairfield Chamber of Commerce. The seminar included workshops featuring **Jay L. Meizlish, M.D.**, a Fairfield cardiologist, and **Edward M. Staub, M.D.**, a Fairfield orthopedic surgeon. Dr. Longstreth serves as the Vice President of the Chamber's Professional Division.

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BRIEF SUMMARY

CONTRAINDICATIONS

There are no known contraindications to the use of sucralfate.

PRECAUTIONS

Duodenal ulcer is a chronic, recurrent disease. While short-term treatment with sucralfate can result in complete healing of the ulcer, a successful course of treatment with sucralfate should not be expected to alter the post-healing frequency or severity of duodenal ulceration.

Drug Interactions: Animal studies have shown that simultaneous administration of CARAFATE (sucralfate) with tetracycline, phenytoin, digoxin, or cimetidine will result in a statistically significant reduction in the bioavailability of these agents. The bioavailability of these agents may be restored simply by separating the administration of these agents from that of CARAFATE by two hours. This interaction appears to be nonsystemic in origin, presumably resulting from these agents being bound by CARAFATE in the gastrointestinal tract. The clinical significance of these animal studies is yet to be defined. However, because of the potential of CARAFATE to alter the absorption of some drugs from the gastrointestinal tract, the separate administration of CARAFATE from that of other agents should be considered when alterations in bioavailability are felt to be critical for concomitantly administered drugs.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Chronic oral toxicity studies of 24 months' duration were conducted in mice and rats at doses up to 1 gm/kg (12 times the human dose). There was no evidence of drug-related tumorigenicity. A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment. Mutagenicity studies were not conducted.

Pregnancy: Teratogenic effects. Pregnancy Category B. Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to sucralfate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sucralfate is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Adverse reactions to sucralfate in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 2,500 patients treated with sucralfate, adverse effects were reported in 121 (4.7%).

Constipation was the most frequent complaint (2.2%). Other adverse effects, reported in no more than one of every 350 patients, were diarrhea, nausea, gastric discomfort, indigestion, dry mouth, rash, pruritus, back pain, dizziness, sleepiness, and vertigo.

OVERDOSAGE

There is no experience in humans with overdosage. Acute oral toxicity studies in animals, however, using doses up to 12 gm/kg body weight, could not find a lethal dose. Risks associated with overdosage should, therefore, be minimal.

DOSAGE AND ADMINISTRATION

The recommended adult oral dosage for duodenal ulcer is 1 gm four times a day on an empty stomach.

Antacids may be prescribed as needed for relief of pain but should not be taken within one-half hour before or after sucralfate.

While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been demonstrated by x-ray or endoscopic examination.

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Reference:

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CONNECTICUT MEDICINE, MARCH 1989

Meckel's Diverticulum in the Pediatric Surgical Population

COLLEEN BROPHY, M.D. AND JOHN SEASHORE, M.D.

Abstract—Meckel's diverticulum is the most common congenital anomaly of the gastrointestinal tract. We reviewed our experience with 31 cases of Meckel's diverticulum in children from 1966 to 1987. Twenty-four patients presented with clinical manifestations: ten from bleeding, ten from obstruction, and four from diverticulitis. Seven Meckel's were incidental findings at laparotomy. Fifty percent of the patients with bleeding had abdominal pain and 100% had ectopic gastric mucosa in the Meckel's. In six cases the technetium scan identified the Meckel's; there was one false negative scan. Obstruction secondary to a Meckel's diverticulum was due to an internal hernia in five and to intussusception in five. Three patients with intussusception had concomitant bleeding. Diverticulitis was clinically similar to appendicitis. There were no complications and no deaths following surgical resection of Meckel's diverticulum.

Introduction

MECKEL'S diverticulum is the most common congenital anomaly of the gastrointestinal tract,¹ occurring in about 2% of the population.² Meckel's diverticula most often present as incidental findings at autopsy or laparotomy but 8-22% of Meckel's will present with symptoms from the diverticulum.¹

In an effort to clarify the clinical presentation of symptomatic Meckel's and the pathologic correlates with clinical disease, we reviewed our experience with 31 cases of Meckel's diverticula.

Results

From 1966-1987, 31 children had resection of a Meckel's diverticulum. Seven Meckel's were removed incidentally during other operations and 24 were removed for symptoms. The ages ranged from newborn to 17 years, with an average age of four years; there were 18 males and 13 females.

Ten patients presented with gastrointestinal bleeding, ten with obstruction, and four with diverticulitis. Bleeding was described as melanic stool in six patients and

bright red blood in four patients. Five of the ten patients had abdominal pain in addition to the bleeding. The pain was usually characterized as crampy; it was acute in four patients and had been present intermittently for four months in one patient. Seven patients had a 99mTc-pertechnetate scan which was positive in six (Fig. 1). In six patients the bleeding was severe enough to require transfusion. All patients with bleeding from a Meckel's diverticulum had ectopic mucosa and five of ten had an ulcer in the adjacent ileal mucosa.

Obstruction was due to a band in five patients and to intussusception in five. Patients less than one year old presented with vomiting and lethargy, and those over one with vomiting and abdominal pain. Three patients with obstruction due to intussusception had prior episodes of rectal bleeding and crampy abdominal pain suggesting intermittent intussusception.

Meckel's diverticulitis was clinically similar to appendicitis; perforation occurred in three of the four patients.

Simple diverticulectomy was performed in 26 patients. Five patients had a segmental resection. Appendectomy was performed in 18 of 24 cases. There were no complications or deaths in this series.

Seven patients had an incidental diverticulectomy, three associated with an appendectomy, two omphalocele repair, one choledochal cyst, and one duodenal atresia. Meckel's diverticula that were discovered incidentally but not removed are not included in this study.

Discussion

The first recorded observation of an ileal diverticulum was by Fabricius Hildanus in 1650.⁴ In 1745 Littre described the presence of a diverticulum in a hernia.⁵ It was not until 1809 that Johann Friedrich Meckel recognized the association of the diverticulum with the omphalomesenteric duct and, in doing so, accurately delineated the anatomy and embryology of the structure that bears his name.⁶ Subsequent observations include the description of a small bowel obstruction secondary to a Meckel's diverticulum by Kuttner in 1898,⁷ the presence of ectopic gastric mucosa in a diverticulum by Salzer in 1904,⁸ and Meckel's diverticulitis mimicking appendicitis by Gramen in 1915.⁹

COLLEEN BROPHY, M.D., Postdoctoral Fellow, Department of Surgery. JOHN SEASHORE, M.D., Professor, Section of Pediatric Surgery, both of the Yale University School of Medicine, New Haven, CT.

Meckel's diverticulum results from failure of complete obliteration of the vitelline (omphalomesenteric) duct. The vitelline duct joins the yolk sac with the gut and is



Figure 1

99mTc-pertechnetate scan. The arrow points to the Meckel's diverticulum in the positive scan.

usually obliterated during the fifth to the seventh week of gestation when the placenta replaces the yolk sac as the source of nourishment for the fetus. Persistence of all or part of the duct can result in numerous anomalies, including a fistula, an enterocystoma, a fibrous band, or, most commonly, a Meckel's diverticulum.^{10,11} The blood supply of a Meckel's diverticulum is derived from the paired vitelline arteries; normally the left artery involutes and the right forms the superior mesenteric artery. Vestigial remnants of the vitelline arteries may connect with the abdominal wall or to the small intestine mesentery forming a band around which a volvulus or internal hernia may develop.

Pathologically, a Meckel's diverticulum is a true diver-



Figure 2

Obstruction secondary to a Meckel's diverticulum. On the left is an intraoperative photograph of an intussusception secondary to a Meckel's. After reduction of the intussusception a large Meckel's diverticulum is seen on the right photograph.

ticulum containing all layers of the intestine. It arises on the antimesenteric border of the ileum, usually within 90cm of the ileocecal valve. Thirty to fifty percent of Meckel's diverticula contain ectopic gastric, pancreatic, colonic, duodenal, or endometrial tissue.¹² In this series 58% of symptomatic Meckel's contained ectopic mucosa, whereas none of the incidentally removed diverticula contained ectopic mucosa.

99mTc-pertechnetate scans have been used to identify a Meckel's diverticulum preoperatively.^{14,15} The specificity of 99mTc-pertechnetate scanning is 95%, and the sensitivity 85%, for a diagnostic accuracy of 90%.¹⁶ False positive scans may arise if enteric duplications containing ectopic mucosa are present. False negative scans arise if there is an absence of gastric mucosa, hypermotility secondary to brisk bleeding with a washout effect, or if overlapping images (bladder or stomach) obscure the Meckel's. In this series six scans were positive and there was one false negative scan (Fig 1).

Eight to twenty-two percent of Meckel's present with symptoms; the remaining are discovered incidentally at laparotomy or at autopsy.¹ In this series 24 cases of Meckel's diverticulum resulted in clinical manifestations, and seven were incidental findings at laparotomy. Bleeding and obstruction were the most common clinical presentations, with diverticulitis more rarely encountered in the pediatric group. Although bleeding secondary to a Meckel's diverticulum is usually described as painless,¹³ half of the patients with bleeding Meckel's in this series had concomitant abdominal pain. All of the patients with bleeding had ectopic gastric mucosa, and 50% had an ileal ulcer. Bleeding from a Meckel's is usually self-limited, but 70% of patients in this series with bleeding required a transfusion.

Meckel's diverticula may cause intestinal obstruction from intussusception, volvulus around a vitelloumbilical band, an internal hernia through a mesodiverticular band, incarceration in a hernia (Littre), or adhesions or stricture secondary to previous inflammation. One half of patients in this series had obstruction secondary to intussusception and the other half to an internal hernia from a band. In patients with a history of earlier episodes of rectal bleeding and abdominal pain, intermittent obstruction secondary to intussusception must be considered and occurred in three of our patients.

The surgical management of a Meckel's diverticulum requires either a diverticulectomy or, if the base of the diverticulum is wide or inflamed, a segmental small bowel resection. In addition, surgical resection should be considered in patients with bleeding because the bleeding ulcer may be in the adjacent ileum. In 80% of the cases in this series a simple diverticulectomy was done; an incidental appendectomy was performed concurrently in 75% of cases. There were no complications or deaths secondary to surgery for a complicated Meckel's diverticulum in this series.

The surgical management of an incidentally discov-

ered Meckel's diverticulum remains controversial. It involves a balance of the risks of diverticulectomy against the risks of a patient becoming symptomatic sometime during his or her life and the added risk of removing a symptomatic diverticulum. Soltero estimated the life-

Table 1

	Bleeding	Obstruction	Diverticulitis	Total Symptomatic
Number of patients	10	10	4	24
Ectopic mucosa	10	3	1	14
Ileal ulcer	5	1	0	6
Considered pre-op	10	5	1	16

time risk of developing symptoms from a Meckel's as 4%.¹⁷ Ectopic mucosa and the presence of a band correlate with the development of symptoms.¹² Although it is difficult to recognize from gross, external inspection which diverticula are likely to contain ectopic mucosa, some clues include palpable nodules, peridiverticulitis, scarring, and inflammatory adhesions.¹

In conclusion: 1) An incidentally discovered Meckel's diverticulum should be removed if there is a band present, if there is a suggestion of ectopic mucosa, if scarring or inflammation is present, or if it will not jeopardize the intended operation at which the Meckel's is discovered, 2) Bleeding from a Meckel's diverticulum is often accompanied by abdominal pain and is often profuse enough to warrant transfusion, and 3) The morbidity and mortality associated with removing symptomatic Meckel's diverticula in the pediatric surgical population is negligible.

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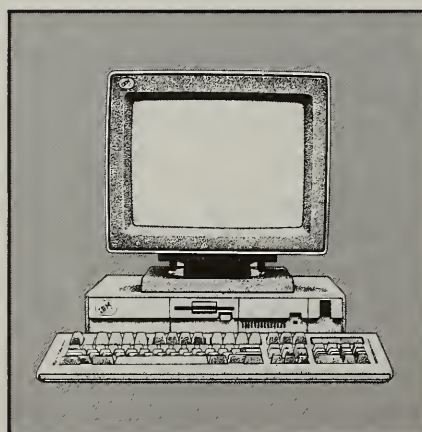
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Dysgerminoma: A Study of 13 Cases from the Connecticut Tumor Registry

JOHN P. KOULOS, M.D., AND JAMES S. HOFFMAN, M.D.

ABSTRACT—Thirteen cases of patients with dysgerminoma of the ovary, accrued from the Connecticut Tumor Registry from 1974-84, were reviewed. Seven of the 13 patients were stage I at the time of initial surgery. Two of these patients had a diagnosis of dysgerminoma arising within a gonadoblastoma. Five of the seven patients were treated with some form of adnexal surgery; one patient received adjuvant combination chemotherapy consisting of vincristine, dactinomycin, and cyclophosphamide (VAC) and another received radiation therapy. Two of the seven patients were treated with total abdominal hysterectomy and bilateral salpingo-oophorectomy (TAH/BSO) plus radiation therapy. One patient, whose tumor recurred after initial therapy with unilateral oophorectomy, was successfully treated with radiation therapy. Six patients had advanced disease at the time of initial surgery. One patient with stage II disease and three patients with stage III disease were treated with TAH/BSO plus radiation therapy. One patient with stage III disease was treated with unilateral adnexectomy plus combination chemotherapy consisting of vinblastine, bleomycin, dactinomycin, cyclophosphamide, and cisplatin (VAB-VI). One patient with stage IV disease was treated with decompressive laminectomy with tumor resection, removal of left pelvic mass, radiation therapy and adjuvant combination chemotherapy (VAC). In our series, no patient died from dysgerminoma (one patient died of an apparently unrelated cause). The role of radiation therapy in the treatment of advanced and recurrent dysgerminoma has been demonstrated. However, the use of combination chemotherapy has been playing an increasingly important role in patients treated with conservative surgery in which preservation of fertility is a concern.

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Presented at the New England Association of Gynecologic Oncologists, June 25, 1988.

Introduction

GERM cell tumors of the ovary account for approximately 15% to 20% of all ovarian neoplasms. The dysgerminoma is the most common malignant germ cell tumor of the ovary. Of the malignant tumors which develop in patients with gonadal dysgenesis, dysgerminoma is the most prevalent. Patients with dysgerminoma carry a very favorable outlook, even with metastatic spread. Radiation therapy has been highly successful because of the tumor's radiosensitivity. Recently, however, conservative surgery, along with combination chemotherapy, has gained greater acceptance, especially for patients interested in preserving reproductive potential. In this study we examined the clinical management and treatment of cases of dysgerminoma of the ovary as recorded by a population-based cancer registry.

Materials and Methods

Case histories of female patients with pure dysgerminoma of the ovary diagnosed from 1974-84 were reviewed from the Connecticut Tumor Registry (CTR) records. The CTR is a population-based registry that accrues data primarily from hospital and clinic records throughout the State of Connecticut with a small number of cases reported from death certificates and private physicians' offices. Only cases of pure dysgerminoma were included in this study. Dysgerminomas containing elements of other malignant germ cell tumors, such as immature teratoma, endodermal sinus tumor, or choriocarcinoma, were excluded. Clinical data were collected from CTR records, hospital medical records, and correspondence with patients' physicians. Follow-up information was obtained in all cases.

Results

Thirteen patients with dysgerminoma were collected from the CTR over an 11-year study period from 1974-84. The ages of the patients ranged from 15 to 38 years, with a median age of 21 years.

Table 1 details the stage, treatment (surgery, chemotherapy, radiation therapy), and the outcome of all 13 patients. Seven of the 13 patients were stage I at the time

Table 1
Treatment of Dysgerminoma
Connecticut Tumor Registry (1974-84)

<i>Stage</i>	<i>(No. of Pts.)</i>	<i>Treatment^a</i>
I	(7)	(1) UO ^b (1) BSO (2) USO + RT (1) USO + VAC (2) TAH/BSO + RT
II	(1)	(1) TAH/BSO + RT
III	(4)	(3) TAH/BSO + RT ^c (1) USO + VAB-VI
IV	(1)	(1) USO + decompressive laminectomy + RT + VAC

^a No patients died from dysgerminoma.

^b Recurrence - subsequently treated with TAH/BSO + RT = NED

^c One patient died at 35 months secondary to an apparently unrelated cause.

UO = unilateral oophorectomy

USO = unilateral salpingo-oophorectomy

TAH = total abdominal hysterectomy

BSO = bilateral salpingo-oophorectomy

RT = radiation therapy

VAC = vincristine, dactinomycin, and cyclophosphamide

VAB-VI = vinblastine, bleomycin, dactinomycin, cyclophosphamide, and cisplatin

of initial surgery. Two patients had a diagnosis of dysgerminoma arising within a gonadoblastoma. Four patients were initially treated with some form of unilateral adnexal surgery (oophorectomy or salpingo-oophorectomy) with or without the addition of postoperative adjuvant combination chemotherapy or radiotherapy. One patient underwent bilateral salpingo-oophorectomy only. The two remaining patients underwent total abdominal hysterectomy and bilateral salpingo-oophorectomy (TAH/BSO) with the addition of postoperative whole abdominal-pelvic radiation therapy. In the stage I group, all seven patients are alive with no evidence of disease. Recurrence occurred in one patient who was initially treated with unilateral oophorectomy only. She was subsequently successfully treated with TAH, unilateral salpingo-oophorectomy (USO) and whole abdominal radiotherapy and remains with no evidence of disease (NED).

Six patients had advanced disease at the time of initial surgery. Four patients were treated with TAH/BSO plus radiation therapy. One patient who had stage III diagnosis was treated with unilateral salpingo-oophorectomy plus combination chemotherapy consisting of vinblastine, bleomycin, dactinomycin, cyclophosphamide, and cisplatin (VAB-VI). One patient with stage IV disease was treated with decompressive laminectomy with tumor resection, removal of pelvic mass, radiation therapy plus combination chemotherapy consisting of vincristine, dactinomycin, and cyclophosphamide (VAC). One stage III patient, who had been treated with TAH/BSO plus radiotherapy remained NED for 35 months but subsequently died of an apparently unrelated cause.

Discussion

Dysgerminoma is the most common type of malignant germ cell tumor, accounting for up to 2% of all ovarian malignancies. This neoplasm, which is similar to the testicular seminoma, is composed of germ cells that are similar to primordial germ cells. Microscopically, the tumor is composed of aggregates of large polygonal cells with vesicular nuclei containing one or more nucleoli and is often infiltrated by lymphocytes and foreign body giant cells.¹ In about 5% of dysgerminomas, syncytiotrophoblastic giant cells, which are the source of increased levels of gonadotropin, may be present.² Dysgerminoma is the most prevalent type of malignant tumor arising in the patients with gonadal dysgenesis.

The use of adjuvant radiotherapy over the past three decades has had a significant impact on the high cure rate for dysgerminoma. Lucraft reported a five-year survival rate of 85% in 33 cases of ovarian dysgerminoma between 1943 and 1977; he emphasized the role of radiotherapy in advanced disease cases, and recommended reserving radiotherapy for recurrent disease in unilateral stage I disease.³ In the series of Krepert, 31 of 36 patients received postoperative radiation therapy. Ninety-two percent receiving initial treatment at this institution and 70% of those referred for treatment after recurrence survived with no evidence of disease.⁴

The role of conservative surgery with or without the use of adjuvant radiotherapy or chemotherapy has recently raised considerable controversy. In a review article by Thomas,⁵ the results of treatment of 145 patients with stage IA disease from three large series were examined.⁶⁻⁸ When these patients were treated with conservative surgery consisting of unilateral oophorectomy with or without ipsilateral salpingectomy, 24% relapsed, but salvage therapy with radiation therapy was successful in 65%. Their overall 10-year survival of 91% was similar to the 85% 10-year survival in a group of 53 patients who initially received nonconservative therapy for stage IA disease.

For patients with advanced stage disease, the addition of radiotherapy had demonstrated success in several series. LaPolla reviewed the results of therapy in 50 patients with stage III dysgerminoma compiled from seven series utilizing primary radiotherapy since 1976.⁹ He reported a death rate of 32% (16 patients: 15 from progressive disease and one from intestinal radionecrosis). Four patients from our series with advanced disease were successfully managed with TAH/BSO plus radiotherapy.

Much of the therapeutic considerations for dysgerminoma have been based on prior experience with the testicular counterpart, seminoma. Chemotherapy has demonstrated good response rates in patients with advanced seminoma, especially with cisplatin-containing regimens. Einhorn utilized vinblastine, bleomycin, and cisplatin.¹⁰ Memorial Hospital reported an 86% com-

plete remission in 28 patients with advanced seminoma utilizing VAB-VI (vinblastine, bleomycin, dactinomycin, cyclophosphamide, and cisplatin).¹¹ From our series, one patient with stage III was successfully treated with this chemotherapy regimen after conservative surgery (unilateral adnexectomy). Schwartz reported five patients with pure dysgerminoma from his series of malignant germ cell tumors.¹² Of interest was one patient (also reported in our series) who presented with lower extremity paralysis and who underwent decompressive laminectomy at which metastatic dysgerminoma was found. After laparotomy revealed a dysgerminoma, the patient was successfully treated with radiation therapy to the pelvis and central nervous system sites and with VAC chemotherapy. Bianchi reported on 11 stage III dysgerminoma patients treated primarily with chemotherapy after surgery.¹³ Of seven patients treated with doxorubicin and cyclophosphamide and five patients treated with displatin, vinblastine, and bleomycin (PVB), nine of 12 patients achieved complete remission with the three remaining patients subsequently successfully treated with radiation therapy with or without PVB chemotherapy. Gershenson treated two patients with metastatic ovarian dysgerminoma successfully with PVB chemotherapy.¹⁴

Our recommendation for the treatment of dysgerminoma would be conservative surgery with unilateral adnexectomy for properly staged IA patients. Chemotherapy or radiotherapy may be withheld if the patient's course can be carefully followed for possible recurrence. For cases of metastatic dysgerminoma, aggressive surgical extirpation with radiotherapy has been shown to yield excellent results. However, an acceptable alternative in these patients who desire preservation of fertility would be a conservative surgical approach with combination chemotherapy. Second-look laparotomy to assess tumor

status would be helpful in these patients in order to plan further radiotherapy and/or chemotherapy if necessary.

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Practical Aspects of Pain Management in Cancer Patients

PETER K. SCHAUER, M.D., WILLIAM AGOSTINUCCI, RPH.,
RICHARD GANNON, PHARM.D., AND ANNELIEKE R. SCHAUER, R.N.

WHEN first confronted with the difficulty of managing cancer patients' pain as a house officer, it became obvious to me that this was an area not adequately covered during my medical school training. Although there have been several excellent reviews of pain management¹⁻³ and the Canadian Medical Association has produced a superb monograph entitled "Pain in Cancer," housestaff still find the lack of education in pain management a major stumbling block that clinically results in inadequate pain control.⁴ We believe pain management can be improved by applying basic pharmacologic principles of analgesics, using basic pain control guidelines, and by learning to ask patients appropriate questions.

There are two reasons for poor pain control by physicians.

1. Lack of factual knowledge, resulting in
 - inadequate doses of narcotics ordered
 - inadequate doses of narcotics administered
 - the "PRN" use of analgesics
 - failure to titrate the dose to the individual patient
 - failure to use coanalgesics and nondrug therapy
2. Inappropriate attitudes and fears
 - the belief that cancer inevitably produces pain and that this pain is uncontrollable
 - fear of addiction
 - fear of respiratory depression

By providing physicians in training with a framework of information upon which to build, pain management can be considerably improved.

Assessment - The first step in pain management is to make an adequate assessment of the patient.

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History - Remember that pain is subjective and the patient is the best judge of the amount of pain present.

Site & Radiation - "Where is it? Where does it go?"

Timing - "How long has it been there? Does it come and go or is it constant?" "Does the pain medication change it?"

Quality - "Can you describe the pain? Is it a dull ache, sharp, throbbing, or burning sensation?"

Severity - "How severe is the pain? How would you rate it on a scale from 1 to 10 with '1' being very mild and '10' being the worst possible, most excruciating pain?"

Aggravating Factors - "What brings on the pain or worsens it, eating, posture, movement?"

Relief - "What relieves it?"

Keep in mind that chronic pain is not simply a perception of a sensation but that there are always emotional components. In view of this, also try to assess what impact pain has on sleep (insomnia), on mood (depression), and on functional status (ability to work, to do things around the house, to go out, etc.). Most importantly, try to assess the effects of prior therapy.

What drugs have been used? (Quantifying prior analgesic use will be essential in ordering further analgesics.)

- What dose, on an ATC (around the clock) or PRN (as needed) basis?
- What is the patient's view of the efficacy of these drugs?
- What was the duration of drug use?
- What was the route of administration?
- What was the interval between doses?
- What side effects did the patient experience?
- Why was the medication stopped?

Physical Examination

Always examine the patient with an eye to finding the cause of the pain. Table 1 outlines potential causes of cancer-related pain. A trite but useful aphorism is that cancer patients get other diseases too, and it is important to rule out nonmalignant causes of pain that may respond to simple treatment.

Table 1
Causes of Cancer-Related Pain

<i>Pain Caused by Cancer</i>	<i>Pain Caused by Therapy</i>	<i>Pain Caused by Unrelated Factors</i>
Bone metastases (+/- muscle spasm)	Constipation	Musculo-skeletal
Nerve compression	Bedsore	Arthritis
Visceral Involvement	Candida/Herpes	Cardiovascular
Soft Tissue Infiltration	Phlebitis	
Elevated Intracranial Pressure	Postoperative Pain (acute)	
	Phantom Limb Pain	
	Postradiation Therapy	
	- inflammation	
	- fibrosis	
	myelopathy	
	Bone Necrosis	
	Chemotherapy-induced Neuropathy	

(After Twycross and Lack, 1983)

Therapy

Physicians in training more often treat patients with acute pain than patients with chronic pain, and this may explain why many students and housestaff find chronic pain difficult to manage. Table 2 summarizes several differences between the treatment of acute and chronic pain. These differences also may explain why meperidine (Demerol®) can be so widely used in the postoperative setting yet has almost no role in the management of chronic pain. Table 3 gives the equivalent doses for the most commonly used narcotics, and it is not an accident that morphine is at the top of the list as morphine remains the "gold standard" for the treatment of severe, chronic pain.

Table 2
Acute Versus Chronic Pain

<i>Aim</i>	<i>Acute Pain Relief</i>	<i>Chronic Pain Relief</i>
Sedation	May Be Desired	Usually Undesirable
Desired Duration of Effect	Variable	Long
Timing	PRN	ATC
Dose	Standard	Must be Individualized
Adjunctive Measures	Usually not Needed	Required

(After Twycross and Lack, 1983)

Morphine

Morphine should be the first line narcotic for the treatment of severe chronic cancer pain. No other narcotic has morphine's flexibility in possible routes of administration and dosage forms. Neither heroin nor "Brompton's Cocktail" (an irrational combination of morphine, cocaine, alcohol, chloroform water often with a phenothiazine added) have been shown to be superior to morphine.^{5,6} Currently, the most useful oral dosage forms of morphine are the sustained-release products. There are 30mg and 60mg tablets (MS-Contin®, Roxanol-SR®) that provide adequate analgesia when dosed every eight to 12 hours. These tablets should never be used on a "PRN" basis and they are not scored and should not be crushed or broken. A patient's starting

Table 3
Commonly Used Narcotics

<i>Drug</i>	<i>Parenteral Equivalent Dose (mg)</i>	<i>Parenteral Potency Factor</i>	<i>Parenteral To Oral Conversion Factor</i>	<i>Equipotent Oral Dose (mg)</i>	<i>Narcotic Antagonist</i>
Morphine	10	1	2-3	20-30	
Buprenorphine (Buprenex®)	0.3	33	not available orally		x
Codeine	120	0.08	1.5	180	
Hydromorphone (Dilaudid®)	2	5	4	8	
Hydromorphone Suppository	Each 3 mg hydromorphone suppository is equal to 5mg parenteral morphine				
Levorphanol (Levodromoran®)	2	5	2	4	
Methadone (Dolophine®)	10	1	2	20	
Meperidine (Demerol®)	100	0.1	3	300	
Nalbuphine (Nubain®)	10	1	not available orally		x
Oxycodone	Not available in parenteral form			20	
Pentazocine (Talwin®)	70	0.14	2	140	x
Propoxyphene (Darvon®)	Each 65mg tablet is approximately equal to 2-2.5mg of parenteral morphine				

dose of sustained-release morphine will depend on the patient's prior narcotic requirement. For example, if a patient was taking two Tylox® or Percocet® every six hours with inadequate pain control, then we would start 30mg of sustained-release morphine every 12 hours. If a patient was taking 6mg of hydromorphone (Dilaudid®) every four hours with inadequate pain relief, then we would start 60mg of sustained-release morphine every 12 hours.

There are other oral dosage forms of morphine, the immediate-release tablets (15mg & 30mg) and oral solutions (10mg/5cc, 20mg/5cc, and 100mg/5cc) that may be useful for "breakthrough pain" on a PRN basis. It should be noted that the morphine solutions are well absorbed sublingually⁷ and this may be helpful in those patients unable to swallow. Morphine is also available as a 5mg, 10mg, 20mg, and 30mg suppository, and the suppository doses are equivalent to the oral morphine doses. The disadvantage to the nonsustained-release products is that they must be given every four hours to provide adequate analgesia.

For patients not able to take oral or rectal morphine alternative routes of administration include: intramuscular (IM), subcutaneous (SC), continuous intravenous (IV), continuous subcutaneous, epidural, and intrathecal. Every four hours IM or SC morphine may be useful in the short term for patients who have nausea, vomiting, or gastrointestinal obstruction. We have not found that adding hydroxyzine improves analgesia, but it certainly adds to the patient's sedation.

For patients with severe, overwhelming pain or for those patients with nausea, vomiting, no muscle mass, or gastrointestinal obstruction we use an IV morphine infusion. This enables us to rapidly titrate the dose to the point where the patient is comfortable. Morphine infu-

sions are not reserved for "terminal" cases, in fact the goal many times is to switch to an oral or SC regimen that will permit more mobility and discharge from the hospital. For convenience, the pharmacy makes morphine infusions in a 1mg/1cc concentration (100mg/100cc, 250mg/250cc, or 500mg/500cc 5% dextrose or 0.9% saline). As morphine remains stable in solution, the solutions are allowed to hang for 48 hours. The starting dose for the IV infusion will depend on the patient's previous narcotic requirement. As an example, if a patient has required 90mg/24 hours of oral morphine (or an equivalent dose of another narcotic) this would be equivalent to 45mg/day of parenteral morphine. We would therefore start the infusion at 2mg/hour (48mg/day) and titrate the dose by 1-2mg/hour every four hours as needed. We also give a bolus dose of morphine at the time the infusion is increased because just increasing the infusion rate would require approximately 16 hours to reach steady state. We include orders to hold the infusion if the respiratory rate is less than eight per minute and if the systolic blood pressure is less than 90mm Hg or if the patient is oversedated. When needed, the infusion is then resumed at 50-75% of the previous dose.

Hartford Hospital has recently instituted a system of patient controlled analgesia (PCA) that has recently been reviewed.⁸ Continuous SC infusions of morphine are less invasive than IV infusions and may permit home, hospice, or extended care facility discharge for those patients unable to tolerate oral therapy. For SC infusions a 27 gauge butterfly needle is usually inserted into the anterior thigh, and a concentrated morphine solution (50mg/cc) specially formulated by the pharmacy is infused via a portable infusion pump. We feel that the maximum SC infusion rate should be 1cc per hour - this means the maximum dose available for SC infusion is 50mg/hour. The infusion site is changed every three to four days, and with these policies there have been no local site complications (erythema, pruritis, infection). When converting from a morphine IV infusion to a SC infusion we use the same doses.

The use of epidural morphine is increasing. Since this technique is more invasive, it is reserved for patients with severe pain who cannot tolerate systemic narcotics because of adverse effects such as oversedation, agitation, or confusion. Epidural morphine seems to work especially well in patients with neurogenic pain. The first dose of epidural morphine is usually 2-5mg with subsequent doses required every six to 24 hours. Many patients will require a continuous epidural morphine infusion. Bolus and continuous infusion intrathecal morphine has also been used. Bolus doses are usually in the range of 0.1-0.5mg.

Recently, it has been found that morphine metabolites accumulate in patients with renal insufficiency whereas morphine itself does not.⁹ These metabolites have analgesic and respiratory depressant activity, and this may explain the "narcotic sensitivity" that is evident in some patients with renal failure. Naloxone reverses the effects of these metabolites as well as morphine itself.

Levorphanol (Levo-Dromoran®)

Levorphanol is a potent narcotic with good bioavailability that is available as a 2mg tablet and 2mg/cc injection. Its long pharmacokinetic half-life (12 hours) means that with some patients it may be effective when given every six hours. We use it as a PRN medication for "breakthrough" pain when a patient is taking sustained-release morphine or methadone. Disadvantages include its expense, its central nervous system side effects (especially in elderly patients), and its limited availability in community pharmacies.

Hydromorphone (Dilaudid®)

Hydromorphone has no advantage over morphine. It is available as 1mg, 2mg, 3mg, and 4mg tablets; 1mg/cc, 2mg/cc, 4mg/cc, and 10mg/cc injections; 3mg rectal suppositories; and 1mg/5cc cough syrup. The duration of action is only four hours and its oral bioavailability is poor. We use hydromorphone occasionally as a PRN agent for "breakthrough" pain.

Meperidine (Demerol®)

Meperidine has almost no role in the management of chronic cancer pain. It is available as 50mg and 100mg tablets; 50mg/5cc syrup; and 25mg/cc, 50mg/cc, and 100mg/cc injections. The reasons for its being a poor drug include its short duration of action, its poor oral bioavailability, and its CNS toxicity caused by the accumulation of a toxic metabolite (normeperidine). It would require approximately 450mg of oral meperidine to achieve the analgesic effect of 30mg of oral morphine. The accumulation of normeperidine occurs more readily in patients with impaired renal function. High levels of normeperidine cause agitation, tremors, confusion, and even seizures. Meperidine does not have the antitussive benefit of the other narcotics. Meperidine interacts with monoamine oxidase inhibitors (including procarbazine) and may produce agitation, muscle rigidity, headache, hypertension, fever, coma, and seizures.¹⁰

Methadone (Dolophine®)

Methadone is a useful but often overlooked narcotic that is inexpensive and is available as 5mg and 10mg tablets; 10mg/cc injections; and 1mg/cc oral liquid. Although the pharmacokinetic half-life is 24-48 hours, the analgesic effect may only last four to eight hours. Doses of methadone should be changed only every three

to four days as the drug may accumulate resulting in excessive sedation and respiratory depression. A short acting narcotic given on a PRN basis is useful while titrating the dose of methadone. When switching from another narcotic to methadone, we usually decrease the "equianalgesic" dose of methadone by 25-50% to take into account methadone's accumulation.

Oxycodone (Percocet®, Tylox®, Percodan®)

Oxycodone is most frequently prescribed as a combination product with acetaminophen (Percocet® or Tylox®) or aspirin (Percodan®). Tylox® has 500mg of acetaminophen per capsule and Percocet® has 325mg of acetaminophen per tablet. Oxycodone 5mg tablets are commercially available but are usually not available in community pharmacies. A liquid preparation of oxycodone 5mg plus acetaminophen 325mg/5cc has recently become available. Oxycodone products are usually the first line agents prescribed to treat chronic cancer-related pain. If a patient requires more than two tablets of oxycodone (10mg) every four hours, we switch to oral morphine. It should be noted that the amount of acetaminophen given at this dose of Tylox® would approach six grams per day which may cause hepatotoxicity in susceptible patients. We frequently use oxycodone products on a PRN basis for "breakthrough" pain.

Pain Management Guidelines

In ordering strong narcotics for cancer-related pain there are several principles to follow.

1. Use pure agonists.
2. Do not mix agonist/antagonist drugs (see Table 3). By giving a drug such as pentazocine (Talwin®), nalbuphine (Nubain®), butorphanol (Stadol®), or buprenorphine (Buprenex®) to a patient on a chronic narcotic regimen, you may actually precipitate withdrawal symptoms.
3. Switch to stronger narcotics if pain is not being relieved by weaker drugs.
4. Use oral administration when possible. IM injections hurt, and the onset of action is not that much more rapid. Use the SC route when parenteral doses are needed.
5. Use ATC dosing. PRN medications should always be added for "breakthrough" pain.
6. Titrate the dose to the individual.
7. Use adjunctive therapy as indicated. Bone pain may improve with nonsteroidal agents such as Naprosyn® or Trilisate®. Elevated intracranial pressure may respond to steroid therapy, neuropathic pain may improve with Dilantin® or Tegretol®, and if depression is a major problem, antidepressant therapy may be helpful.
8. Use narcotics as part of the total plan including nondrug measures and psychosocial support. It also seems obvious that if the cancer itself can be treated with radiation, surgery, or medical therapy, pain may be markedly reduced.
9. Be aware of the common myths concerning mor-

phine therapy.

Myth: Morphine = Respiratory Depression

Narcotics cause a graded effect on the CNS with increasing doses, therefore you see sedation, confusion, hallucinations, and lethargy well before you see respiratory depression. Respiratory depression is rarely seen even in patients with significant underlying lung disease.

Myth: Morphine = Addiction

The World Health Organization defines drug dependence as "a state, psychic and sometimes also physical, resulting from the interaction between a living organism and a drug, characterized by behavioral and other responses that always include a compulsion to take the drug on a continuous or periodic basis in order to experience its psychic effects, and sometimes to avoid the discomfort of its absence." When used in pain management, craving does not occur, and if pain decreases, morphine can be tapered and stopped, often with minimal withdrawal symptoms.

Myth: Morphine = Rapid Tolerance

This "save it until you need it" myth is particularly common as a fear among patients, but clinical tolerance is quite unusual. If the dose required increases, this often indicates that the cancer is progressing. Tolerance can occur, but this usually develops over prolonged periods of time.

10. There is no maximum dose of a narcotic.

One case serves as an example. S.H. was a 42-year-old white married lady with ovarian cancer who required hospitalization because of pelvic and lumbosacral pain not being controlled with oral narcotics. A morphine infusion was titrated over a 72 hour period to a dose of 300mg of morphine per hour, at which point she was sitting up in bed doing a crossword puzzle. She "finally felt comfortable" and it was remarkable that she was able to leave the hospital requiring no narcotics after a course of radiation therapy resulted in dramatic reduction in the size of the tumor.

11. Address side effects.

Treatment should also be directed toward other symptoms such as nausea, constipation, cough, and dyspnea that may be contributing to the patient's discomfort. Constipation is almost universal with the use of strong narcotics. Table 4 outlines an approach to bowel management for patients on narcotics suggested by Twycross and Lack.¹¹ Antiemetic therapy may be necessary if nausea develops. Urinary retention is an infrequent problem but may occur because of morphine's effect to contract the vesical sphincter and increase the tone of the detrusor muscle. If pain is causing the patient to awaken during the night or early in the morning, increasing the bedtime dose of narcotic or waking the patient on schedule to administer a dose may permit a more comfortable nights sleep.

Table 4
Bowel Management for Patients on Narcotics

1. Check previous bowel/laxative habits
2. Record bowel movements daily
3. Rectal exam to rule out impaction
4. Encourage fluids, prune juice, bran
5. Stool softener/stimulant combinations (PeriColace®, Senokot®)
6. Dulcolax® or lactulose syrup 15-30cc 2-3 times per day as needed
7. Enemas as needed
8. Use bedside commode or raised toilet seats as needed
9. In general avoid bulk laxatives especially if oral fluid intake has decreased

(After Twycross and Lack, 1983)

12. Reevaluate if present therapy is ineffective. Several questions should arise. Is the patient complying with the recommended schedule? Is a larger dose needed? Is the pain unresponsive to morphine (neuropathic or dysesthetic pain)? Is nondrug therapy needed? (An example is the use of a celiac block for pain relief in patients with cancer of the pancreas.) Should an epidural morphine infusion be considered? Is a neurosurgical procedure indicated?

Conclusion

Pain due to malignancy occurs in approximately 40% of all cancer patients and in roughly two-thirds of patients with advanced cancer. The control of pain with currently available medications and techniques is possible in the vast majority of patients, but the total eradica-

tion of all pain is an unrealistic goal. By providing adequate comfort physicians are truly helping patients live with their disease.

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AIDS Patient's Bias Claim Dismissed

A complaint filed by an AIDS patient against a physician who refused to treat him was dismissed by a New York trial court.

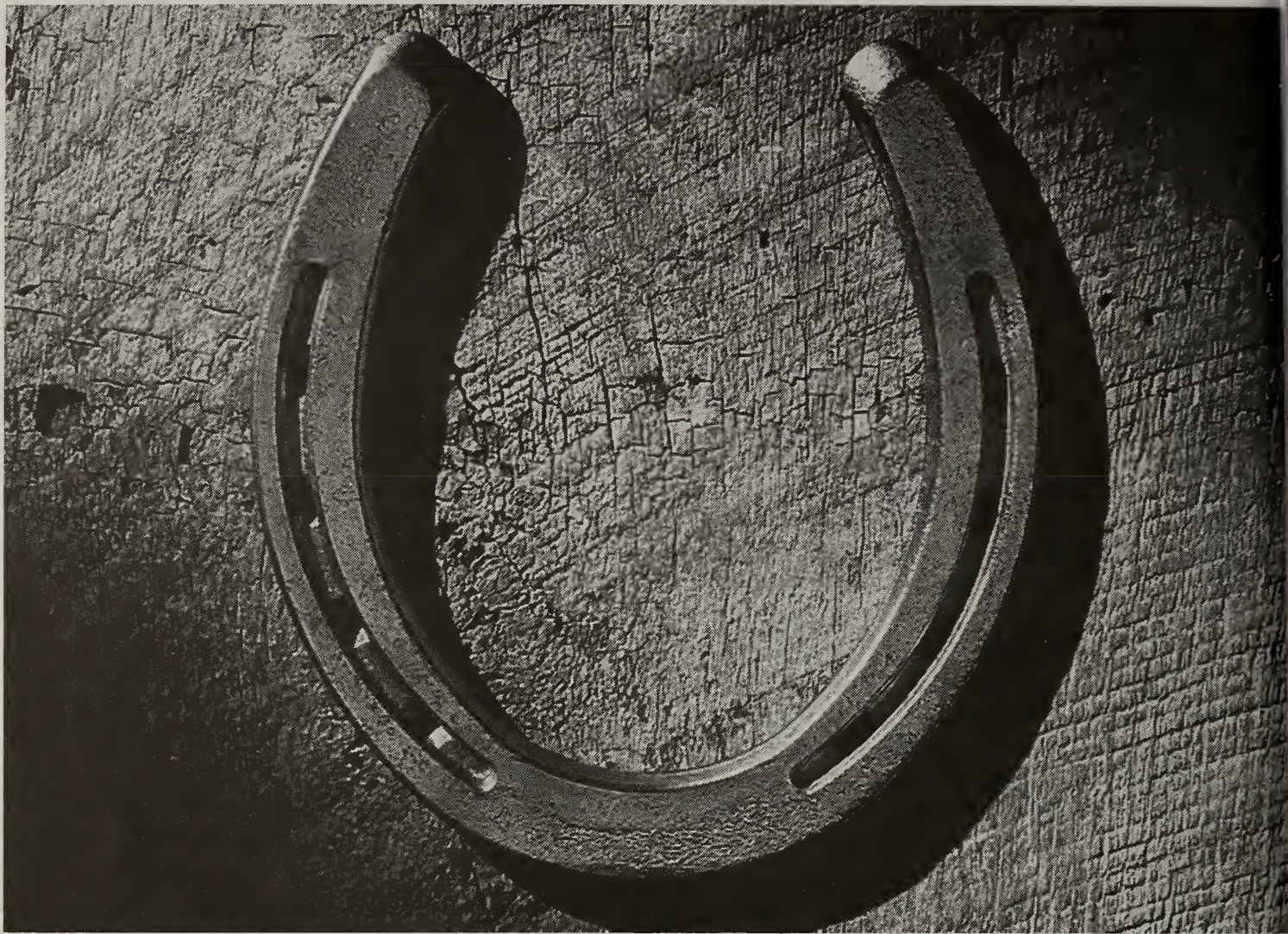
The patient had sought treatment from his regular orthopedist for back, neck and chest ailments. Shortly after the patient disclosed to the physician's staff that he had AIDS, the physician told him that he did not have the expertise to treat AIDS patients, and that the patient should seek care in an AIDS clinic. The patient complained to the State Division of Human Rights, which found grounds for the complaint. The physician brought legal action against the Division, claiming it had no jurisdiction over him or his office.

The statute under which the Division acted makes it unlawful for the owner of any place of "public accommodation" to discriminate on the basis of a number of

characteristics, including disability. The court said it was apparent that AIDS is a disability within the meaning of the law. It is also clear, the court said, that dispensaries, clinics and hospitals are "places of public accommodation."

Nevertheless, the court found that professional medical offices of private physicians are not within the scope of the statute. Reason dictates that physicians' private offices are fundamentally distinct from clinics, dispensaries and hospitals, the court said.

The court also rejected the Division's argument that the physician's office was included within "wholesale or retail stores and establishments dealing with goods or services of any kind." A physician engaged in private practice cannot be compelled to accept an individual as a patient. Accordingly, the court ordered that the patient's complaint be dismissed.—*Elstein v. State Division of Human Rights*, (N.Y. Sup. CT., Aug. 16, 1988) (Source: *New York Law Journal*, Aug. 18, 1988)



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Important Advances in Clinical Medicine

Plastic Surgery

The Scientific Board of the California Medical Association presents the following inventory of items of progress in plastic surgery. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers, or scholars to stay abreast of these items of progress in plastic surgery that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Plastic Surgery of the California Medical Association and the summaries were prepared under its direction.

Treatment of Burned Hands

LIKE the rest of modern burn treatment, the care of burned hands has focused on early excision and grafting. I prefer to excise and skin graft deep partial-thickness wounds even at the risk of removing potentially viable tissue. This type of wound tends to produce hypertrophic scar and stiffness if allowed to heal by granulation and epithelialization. Determining the depth of an injury continues to require the experience and skill of a burn surgeon, although objectively measuring cutaneous blood flow with a laser Doppler is potentially useful.

Following the initial cleaning of a burn wound, the hand is elevated and splinted with the metacarpophalangeal joints flexed to 90 degrees and the fingers straight. The thumb is held in abduction. Superficial burns may be wrapped in protective occlusive dressings or gloves made from synthetic skin (Biobrane) applied. Deeper injuries are treated with topical antibacterials, usually silver sulfadiazine, and observed for several days until edema has resolved. With circumferential burns of the hands and forearms, the possible need for escharotomy to prevent vascular compression is evaluated clinically and by measuring tissue pressure with a wick catheter.

Hand burns that appear likely to epithelialize within two weeks are given a chance to heal on their own. Deeper wounds are excised and skin grafting done as

soon as the patient is stable. A tangential excision that leaves the lower dermis is preferred when the burn has not damaged this layer, as it provides a stable base for the new skin grafts and prevents wounds from contracting. Enzymatic removal of the burn-injured outer dermis is an alternative method of preparing the wound for skin grafting and can even prevent the need for open escharotomies. Unexpanded meshed skin grafts are frequently used and give excellent functional results, but, unmeshed sheet grafts, while technically more exacting, give better cosmetic results.

Patients with newly healed hand burns and grafts frequently require intensive rehabilitation with supervised exercises, dynamic splints, and pressure garment gloves to prevent hypertrophic scar and stiffness. Many patients who in the past would have been left with severe contracture deformities and a future of many reconstructive operations can now realistically look forward to a fully functional and cosmetically acceptable hand after a burn injury.

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Functional Results After Microvascular Operations

MICROVASCULAR surgical techniques have become effective in reconstructing acute and chronic deformities. The overall success rate of replanted parts in most microsurgical centers is about 86%, with laceration type amputations having the lowest success rate (76%). The replant success rate falls off to 60% when the cold ischemia time of a replanted part is longer than 20 hours. The use of medicinal leeches (*Hirudo medicinalis*) has increased the survival of replanted crush-injured parts.

The functional results of digital replantation are encouraging. In a recent review of 142 replanted digits, 31% had excellent results, 54.9% had good results, 10.7% had fair results, and 3.5% had poor results. Results are based on range of motion, sensation, subjective symptoms, cosmesis, and patients' satisfaction.

Microvascular free tissue transplantation is now the method of choice to solve many difficult reconstructive problems. Coverage of the distal third of the tibia, as in grade 3 to 4 open tibia-fibular fractures, is best accomplished by free latissimus dorsi muscle transplantation. The transplanting of serratus anterior muscle or de-epithelialized skin flaps is now used extensively in reconstructing soft tissue deficits of the face in patients with hemifacial atrophy (Romberg's disease), hemifacial microsomia, or in those who have had head and neck cancer resections. Near-symmetric movement in patients with facial paralysis is frequently attained following cross-facial nerve grafting and free serratus anterior muscle transplantation. The success rate of using free flaps averages 93% to 95% in most microsurgical centers.

Toe-to-hand transplantation is now being done on hundreds of patients with traumatic or congenital loss of digits. The transplanted toes function best when the great toe is used for thumb reconstruction and the second toe, from either one or both feet, is used for finger reconstruction. Sensation of the transplanted digit is close to normal: 10- to 20-mm two-point discrimination. Grip strength of transplanted toes is 60% to 80% of that of the uninjured side. In all, 95% of patients have no donor site morbidity and are able to resume their preinjury activity levels.

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Lipoplasty

L IPOPLASTY, or liposuction, has had a profound effect on the practice of plastic surgery, becoming in just five years the most common aesthetic procedure done in the United States.

The techniques used in lipoplasty are conceptually contrary to those used in traditional operations. Surgeons typically work through open incisions, excising tissue with sharp instruments while directly viewing their field of work. A lipoplasty surgeon makes only a small incision through which a blunt cannula, attached to high-powered suction, is passed into the subcutaneous fat. The cannula is moved back and forth in the subcutaneous fat while the tissue is molded with the opposite hand; during this procedure the surgeon is unable to see the tissue directly.

Yves-Gerard Illouz is the originator of the technique of lipoplasty. Using a blunt instrument preserves the fibrous septa, which contain the blood vessels and nerves, coursing vertically in the subcutaneous fat from the deep fascia to the underlying surface of the skin. Preserving the septa allows the skin to collapse, avoiding a pocket that could lead to the accumulation of fluid and its related problems.

Since the introduction of lipoplasty to the United States five years ago, several modifications have been made. Epinephrine has been added to the preoperative wetting solution. A low-dose concentration, approximately 1:400,000, has been shown to reduce the amount of blood present in the fat aspirate by about 50%, thus allowing for the safe removal of greater volumes of fat.

Because of the need for good skin elasticity, it was initially thought that suitable candidates for lipoplasty must be younger than 45 years. Studies have subsequently shown that patients who have satisfactory skin elasticity in their fifth, sixth, or seventh decade make good candidates for lipoplasty, both physiologically and psychologically. Older patients are often better candidates psychologically than younger ones.

Lipoplasty was originally designed for removing accumulations of fat in the torso and lower extremities. More recently it has been effectively used in other sites, specifically the head and neck, and for reconstructive procedures such as the removal of solitary or multiple lipomas and the debulking of flaps. Gratifying results have been attained particularly in the neck in the use of both closed aspirative lipoplasty and lipoplasty combined with rhytidectomy. Interest in its use at other sites such as the knees, calves, and ankles is increasing.

Problems have occurred with the procedure, the more

horrific of which have received national publicity. These appear to be related to the removal of too much fat, the occurrence of infection, or the sequelae of contouring defects. These problems can be reduced with limited fat removal, a proper sterile technique, and well-trained surgeons. Studies indicate that, in qualified hands, the incidence of complication is low.

We now have a safe and effective method of removing subcutaneous fat. Currently used primarily for removing localized fat, the ramifications of the technique have not yet been fully examined. In addition to its effect on plastic surgery, lipoplasty may affect other aspects of the practice of medicine.

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Peripheral Nerve Repair and Regeneration

THE many complex issues surrounding the ideal methods of treating peripheral nerve injuries continue to be a focus of divergent opinions. During the past decade, however, surgeons have generally agreed on the usefulness of thin peripheral nerve grafts for nerve deficits too great to be overcome by approximating proximal and distal stumps by more than modest tension. Also, there is growing consensus that repair techniques that enable surgeons to better match fascicles or groups of fascicles enhance ultimate functional recovery, though a definitive study clearly showing this has not been done.

While fascicular matching techniques and nerve grafting have helped to solve some difficult clinical problems, many remain. Recently, intensive research has led to several new advances toward possibly solving these difficult remaining problems such as severe injuries to the brachial plexus where long gaps between proximal and distal nerve stumps exist.

Laboratory studies have indicated that nerve axonal regeneration across a vascularized nerve graft—a nerve graft that is harvested with its accompanying artery and vein, which can then be sutured by microvascular anastomotic techniques to a recipient artery and vein, providing an ongoing blood supply to the nerve graft segment—may be better than that across standard nerve grafts.

Human anatomic studies have identified several expendable nerves that accompany expendable arteries and veins of a size suitable for microvascular anastomosis. These include the sural nerve, antebrachial cutaneous nerve, radial sensory nerve, and the distal peroneal

nerve. In selected clinical situations, for example, patients with long defects or defects that cross extremely scarred or hypovascular areas, the chances of ultimate functional recovery may be improved.

Recent intensive research into sutureless repair methods has led to the concept of using artificial nerve conduits in place of nerve autografts to overcome deficits of a modest length. Laboratory studies using both rats and nonhuman primates showed that regeneration through a biodegradable nerve conduit was equal to that across standard nerve grafts. The advantage of such a technique, obviating the need to harvest an autograft from a donor site with the potential creation of a painful neuroma, is obvious.

Finally, as experience with tissue expanders grows, surgeons are finding that peripheral nerves can be gradually lengthened by tissue expansion techniques. Laboratory studies indicate that the lengthened segment maintains anatomic and physiologic continuity. By lengthening the distal (denervated) segment, significant nerve gaps might be overcome.

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Gynecomastia

GYNECOMASTIA (Greek *gynec*, denoting “relationship to women,” and *mastos*, “breast”) refers to the presence of femalelike mammary glands in a man or a boy. An incidence as high as 65% in adolescents and 40% in adults has been reported. Most patients are not treated. Adolescents are usually told they will outgrow the problem, and most adults either are told to lose weight or are not sufficiently bothered by its presence to seek treatment.

Considering the high incidence of gynecomastia and the fact that medical treatment is rarely indicated and more likely is contraindicated, surgical treatment should be considered in properly selected patients. Surgical correction is particularly important to counter the self-consciousness and embarrassment that invariably accompany this disorder in adolescence.

Numerous conditions may be associated with gynecomastia. They may be categorized as physiologic (neonatal, pubertal, or involutional), endogenous (testicular, adrenal, thyroid, pituitary, or other), or exogenous (hormones or drugs). In most patients a cause cannot be identified. If it develops slowly and is asymptomatic, the cause may be ignored in an otherwise healthy person. If the gynecomastia began before puberty, the cause should

be investigated. When it begins during puberty, the cause is usually idiopathic. Because 62% of cases of gynecomastia may be drug related, a drug history may be helpful. It should be noted that the extent of gynecomastia of any cause may be greatly asymmetric or even unilateral.

Although carcinoma of the male breast is rare, accounting for 0.2% of all cases of carcinoma in men, should a unilateral, firm, irregular mass be detected on examination, a biopsy should be done. Otherwise, biopsy is unnecessary.

The surgical technique must be adapted to the size and type of gynecomastia and the amount of redundant skin. Whenever possible, the incisions should be done at the border or within the areola without displacing the nipple. Historically, surgical treatment consisted of sharp dissection of the fat and parenchymal tissue that make up the deformity. Undesired sequelae and complications included unattractive scars, contour deformities, and hematoma. Since 1980 many plastic surgeons have been using suction lipectomy as well as sharp dissection in the treatment of gynecomastia. With the addition of suction lipectomy, the incidence of contour deformities and hematomas has decreased. Some patients can be treated with suction lipectomy alone, but most require a combination approach. Suction lipectomy is done first, followed by sharp dissection of any residual parenchyma that requires removal. In general, excellent cosmetic results can be expected from experienced plastic surgeons.

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Head and Neck Reconstruction

TUMOR ablation in the head and neck area has a major functional and aesthetic impact, causing profound changes in the subsequent quality of life. This is especially the case if reconstruction is delayed for fear of masking recurrent disease. This concept is now untenable as computed tomographic (CT) scans and CT-directed needle aspiration biopsies are reliable in detecting disease, even in deep tissues. Further, immediate reconstruction offers the best chance for early rehabilitation. The goals of such reconstruction are to restore speech and swallowing, prevent aspiration and drooling, and produce a primarily healed wound with the least possible deformity.

Two advances in the past ten years have dramatically altered our approach to this problem. McCraw's description of independent myocutaneous vascular territories in 1977 led to the definition of several useful myocutaneous flaps for a head and neck operation. The pectoralis major myocutaneous flap is the most versatile one, offer-

ing a large skin paddle for oropharyngeal or cutaneous replacement and a bulky muscle that can securely cover irradiated carotid vessels. The trapezius and latissimus dorsi myocutaneous flaps have also been used for similar purposes. These single-stage reliable flaps have now replaced temporal, deltopectoral, and multistage tube pedicle flaps.

The second major advance has been in describing fasciocutaneous and compound flaps suitable for microvascular transfer to the head and neck. The radial forearm and parascapular fasciocutaneous flaps have the advantage of thinness and conform well to a three-dimensional defect in the oral cavity and oropharynx. The tethering effect of a bulky myocutaneous flap on the tongue is avoided, thereby enabling better speech and swallowing. The iliac osteocutaneous free flap can be used for immediate, one-stage total mandibular reconstruction, even in previously irradiated fields, eliminating the "Andy Gump" deformity. Replacing the pharyngoesophagus with a revascularized segment of jejunum allows for early swallowing and adequate oral intake as early as one week after the operation. Microvascular reconstruction offers the distinct advantages of functional tissue transfer and a superior aesthetic result. The risk of complete failure due to vascular thrombosis is ever present, however. Microvascular expertise and considerable experience are critical factors for a successful outcome.

It is clear that one-stage immediate reconstruction for head and neck cancer improves the quality of life and shortens the hospital stay. This is especially important when a cure is uncertain and life expectancy is limited.

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Flap Surgery in the 1980s

IN recent years there has been a concentrated national and international effort directed at reexamining the blood supply to the skin. As a direct result of this intensive effort, the number and versatility of available flaps have grown dramatically over the past few years. This has resulted in an ability to treat the most complex injuries and defects. The blood supply to skin, and therefore flaps, has been divided into four basic groups. First, "random flaps" have a blood supply that is entirely dependent on a subdermal vascular network, or plexus.

Beneath this plexus, running on the surface of the deep fascia over the muscle, is another vascular network that communicates with the subdermal plexus through a series of vertical vessels in the subcutaneous tissue.

The elevation of a flap incorporating the deep fascia, the subcutaneous fat, and vessels including the skin is the second group, referred to as a "fasciocutaneous flap," and elevation of the flap, including all of the above with the underlying muscle, is the third, known as a "myocutaneous flap." Perforating vessels running directly from the muscle to the skin through the two perviously mentioned plexuses are responsible for this relative revolution that has occurred in reconstructive plastic surgery. As experience has shown, not only do we have "spare" or expendable muscles available, but the large size of muscles such as the latissimus dorsi muscle or the skin territory supplied by the rectus abdominis muscle, among others, has allowed for the reconstruction or coverage of large defects of complex structures such as the breast after a mastectomy.

Recently it has become evident that the vascular plexus over the fascia may be fed not only from perforators arising from the underlying muscle but also by direct communication from deeper, well-known vessels such as the radial artery or the peroneal artery in the leg, which is the fourth type of blood supply.

The selection of a flap based on these larger vascular pedicles has dramatically improved the versatility and safety of these flaps in reconstructing areas as diverse as the hand and the head and neck. The added ability to include viable bone or even nerves has dramatically increased the range of reconstruction options available. Our improved understanding of the blood supply to skin and underlying structures has now made it possible to reconstruct defects safely in one stage with far less disfigurement to patients and with functional results that, even if possible, were far more complex to achieve just a few years ago.

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Tissue Expansion

TISSUE expansion was introduced to the plastic and reconstructive surgery community in 1976 as an

alternative method for providing ideal and additional local tissue cover. Improved techniques have resulted in shorter hospital stays, decreased morbidity and complication rates, and stable aesthetic and functional reconstructions. In addition, advances in implant design and concepts now permit clinicians to vary their reconstructive procedures by using the expansion technique.

Long-term expansion is a procedure whose end result is similar to the effects on the anterior abdominal wall produced by the enlarging uterus in a pregnant woman. Long-term expansion consists of two stages: first, the expander(s) is inserted; and, second, expanded tissues advance after a period of serial expansions for as long as two to four months. The newly recruited skin may provide near-perfect color, texture, and sensory qualities to match the lost skin. The hallmark of the procedure remains a minimal donor-site scar. At this time, the source(s) for the additional tissue remains unclear but can be attributed to a direct stretching of skin, an inward migration of tissue, or the stimulation of cells to divide and multiply.

Intraoperative expansion is a new technique to stretch tissues during the surgical procedure. The amount of tissue stretched depends on its pliability and extensibility. These characteristics are in part determined by the intrinsic thickness and elasticity of dermis (location, genetic factors, and patient's age) and acquired changes in the characteristics of the tissues (scar, irradiation, and inflammatory changes). Intraoperative expansion differs from long-term expansion by offering the following inherent advantages that reduce the duration of expansion: the absence of a retained, buried foreign body; the absence of a physical deformity, especially in the head and neck areas; and the immediate availability of tissue for reconstruction. The technique most aptly applies to the coverage of small to medium-sized rather than of larger defects.

Directional expansion is possible with the development of expanders that stretch more in one area than another. Thus, during long-term expansion, more tissue may be recruited in a preferred location by the directional bulge of the expander. Directional expansion is currently applied to improve the results of scalp expansion and breast reconstruction.

A tissue expander has been developed that, once inflated to an appropriate size, is left in position as a prosthesis. The remote valve and tubing are withdrawn from the expander under local anesthesia, eliminating the need for a second procedure. The most rapid acceptance of this type of permanent expander has been in the area of breast reconstruction.

Complications have been substantially reduced over the past ten years because of improved patient selection, technique, and surgeon education. An exposure of expander units to contamination and infection has been the major complication of this technique.

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Three-Dimensional Imaging in Surgery

THREE-DIMENSIONAL imaging is a newly established imaging modality based on computed tomographic (CT) and magnetic resonance imaging data. The modality is the result of computer processing of the scan data on a slice-by-slice basis. Using various algorithms, the edges of interest are detected and specific tissues selected for display. These processed cuts are then stacked, interpolated, and shaded to provide a three-dimensional view of the anatomic area of interest. The modality has been useful as an adjunct to diagnosis and surgical planning, with its usefulness extending to the specialties of neurosurgery; orthopedics; plastic and reconstructive surgery; oral surgery; ear, nose, and throat surgery; orthognathic surgery; medical oncology; diagnostic radiology; and radiation therapy planning. Its application to areas of soft tissue analysis is rapidly growing.

The surgical usefulness of the data is enhanced by the ability to interact with the scans to provide cutaway and disarticulated views. Though no new data are added in the process, studies confirm a significant diagnostic advantage in three-dimensional imaging, especially evident in spinal disorders—vertebral and foraminal stenoses, fractures, spinal fusion assessment—pelvic trauma, and craniomaxillofacial problems.

The availability of the process depends on specialized software running either on a CT scanner computer or on one of several add-on image processors. Using scanner software has built-in limitations of appropriating CT scanner time (thus limiting the number of procedures requiring CT) and limited interactivity with the scan data. While usually somewhat more expensive, add-on processors usually process data from multiple scanner manufacturers and permit a full range of interactive two-dimensional and three-dimensional viewing, life-sized representations of data, on-screen metric capability, and volumetric analysis for tumor tracking.

The technology is further extended by the use of the data to drive a numerically controlled machine tool to provide solid, three-dimensional, hands-on models of the bony anatomy of interest for teaching, rehearsing surgical procedures, or designing implantable prostheses.

Third-party reimbursement has been established and requires the proper relative-value schedule coding.

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Congenital Nevi—Risk of Malignancy

THE incidence of malignant lesions in congenital nevi has been estimated to be between 1% and 10%. Size, location, and histologic type seem to be factors. The larger the lesion, the higher the risk. Giant nevi—greater than 100 cm sq—may have an incidence of 5% to 10%. Small congenital nevi have not been adequately studied, but 40% to 60% of melanomas are associated with preexisting small nevi. It has not been established that these small nevi were congenital.

The most common sites for malignant degeneration in giant nevi are the posterior scalp, neck, back, and buttock; 80% of malignant lesions occur in these areas. There is a lower risk of malignancy in giant nevi of the face and extremities, but the reason for this differential risk is not known.

The most common age for a malignant lesion is during the first year of life. High risk is encountered also during early childhood, and then the risk is reduced during puberty and later life. Early excision is therefore indicated when feasible.

The treatment of choice is complete excision of a nevus through the level of the subcutaneous tissue, accompanied by replacing the skin with either full-thickness skin grafts or flaps. The method of skin replacement and the sequencing of the excision are determined by the size and location of the lesion. Full-thickness skin grafts are used on various parts of the face. Whenever possible, the skin on the trunk and extremities is expanded subcutaneously with silicone inflatable prostheses. This method is ideal for giant nevi of the scalp. Dermabrasion with a mechanical dermatome, or dermabrasion, is used only as a compromise treatment because only the superficial half of the lesion is removed and the neval cells in the deep dermis and around hair follicles remain. The malignant potential of the residual nevus is not known. Although dermabrasion was initially advised only during infancy, it can be done at any age. The pigmentation is greatly reduced, but hair follicles remain.

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National Board Endorses Proposal For Single Licensure Examination

At the National Board of Medical Examiners' (NBME) annual meeting in Philadelphia on March 30 and 31, the board considered a proposal for a single examination for medical licensure. The proposal, which was developed by a multi-organizational task force, would provide a three-examination sequence for all candidates for licensure in the United States.

The first two examinations would be similar to the National Board's Part I and II, and the third would be an adaptation of the Federation Licensing Examination (FLEX). Graduates of both Liaison Committee for Medical Education (LCME) and non-LCME accredited medical schools would be required to pass the same examinations.

The Educational Commission for Foreign Medical Graduates would require the first two examinations for certification of candidates for entry into graduate medical education. This would replace the current Foreign Medical Graduates Examination in the Medical Sciences. The FLEX examination would no longer be used as a separate licensing exam.

After a thorough discussion, which included exploration of the effect a single examination system might have on the certification of LCME graduates by the National Board, the board endorsed the proposal and approved the development of an implementation plan to be considered at next year's annual meeting. This proposal also will be placed on the agenda of the other organizations

involved in the task force, including the AAMC.

The board also endorsed a five-year plan developed by the NBME staff and executive board. The plan covers five major activities:

- Establishing the future role of the National Board in medical licensure in the United States
- Development of new assessment methods
- Improving the evaluation services provided to medical schools
- Assuring the quality of all NBME testing programs
- Improving the institutional infrastructure, including modernization of the computer systems and reevaluation of space needs

L. Thompson Bowles, M.D., Ph.D., vice president for medical affairs and executive dean of the George Washington University School of Medicine and Health Sciences, was elected to a second two-year term as chairman of the board. David S. Citron, director of the Federation of State Medical Boards, was elected vice chairman, and Edward J. Stemmler, M.D., executive vice president of the medical center, University of Pennsylvania School of Medicine, was elected treasurer. Walter F. Leavell, M.D., president, Charles R. Drew University of Medicine and Science, and F. Marian Bishop, Ph.D., chairman of Family and Preventive Medicine, University of Utah School of Medicine, were also elected to the executive board.

(For more information, contact Vice President for Academic Affairs August G. Swanson, M.D., 202-828-0475.)

—Association of the American Medical Colleges Weekly Report, April 6, 1989.

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Boswell's Affective Illness: A Reappraisal

HENRY R. KRANZLER, M.D.

ABSTRACT—James Boswell, the noted 18th-century writer, was well known to have suffered from bouts of melancholia, as well as episodic drunkenness, sexual excesses, irritability, and euphoric self-absorption. Drawing upon the writings of both Boswell and his biographers, the present work reconsiders Boswell's affective illness in modern psychiatric diagnostic terms. Boswell appears to have suffered from cyclothymic disorder, a highly prevalent disorder in successful 20th-century writers.

Introduction

PSYCHOHISTORIANS combine the science of reconstruction with the art of conjecture. They seldom walk on *terra firma*, producing results that are often interesting but seldom irrefutable. Such findings can be valuable in helping us to view the workings and motivations of the great minds that preceded us. A notable example is the reinterpretation by Lieb and Hershman¹ of the illness suffered by Isaac Newton. James Boswell has also been the subject of psychohistorical analysis.² Though productive, Boswell was, throughout his life, troubled by episodes of melancholia, which alternated with periods of excess and extravagant self-absorption. In the present paper, the aim is to reconsider Boswell's psychopathology and its relationship to his literary creativity.

A prolific diarist, Boswell is best known for *The Life of Samuel Johnson, LL.D.*, in which he paid homage to his esteemed friend and mentor. Boswell's diaries are voluminous, and though they provide an admittedly one-sided view of his life (both external events and inner experience), his personal appraisal is very thorough and candid. Furthermore, both because of the engaging style in which he wrote and the risqué and exciting life he chronicled, much has been written about Boswell by others.

This reappraisal of Boswell's illness begins with an overview of his life. This is followed by a description of his moods and behavior, using material from both journals and biographical accounts. As a counterpoint to the

interpretations of his moods and behavior provided by his biographers, we apply current psychiatric diagnostic criteria³ to view Boswell's life from a psychopathological perspective.

Boswell was born in Scotland in 1740, the second son of Lord Auchinleck, a noted Edinburgh jurist. Although he had an early penchant for travel and adventure, Boswell acquiesced to his father's wishes that he study law. From 1753-60, he studied classics and law at the Universities of Edinburgh and Glasgow. In 1766, he was admitted to the bar and he practiced law for the remainder of his life.

Boswell, however, fancied himself more of a noble than a jurist, and in 1762 he sought a commission in the Foot Guards, a London military unit. Unable to obtain the commission, he took up the battle for the independence of Corsica as a personal crusade. Ultimately he spent more than a year there and his chronicles of that time provided the basis for his *Account of Corsica*. In 1763, he met Dr. Samuel Johnson, with whom he maintained a lifelong friendship. Boswell later convinced Johnson to travel with him to his beloved Scotland, which was chronicled in his *The Journal of a Tour of the Hebrides with Samuel Johnson, LL.D.*

In 1769, Boswell married a cousin, Margaret Montgomery, who was two years his senior. Prior to their marriage, he had been a notorious philanderer, gambler, and heavy drinker, and the marriage did little to change him.

Boswell kept company with some of the major literary figures of the 18th century, including Goldsmith, Rousseau, and Voltaire, and much of the writing in his diaries concerns these men. Boswell began a "candid and accurate" journal at the age of 18, which he maintained conscientiously during his life. The journal was the basis for most of his published works, which had mostly been carved from his diaries, then arranged and published.⁴ At the time of his death in 1795, Boswell was a recognized literary figure, but it was not until the bulk of his writings were discovered in the early 20th century that he achieved his current recognition.

The Biographers' Views

Much has been written about Boswell's episodes of

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melancholy; other traits have been equally well documented. He was inclined to heavy drinking and his sexual exploits are described in detail in his journals, but generally no effort has been made to relate them to the melancholy. At the age of 17, Boswell had his first episode of severe depression, from which he recovered spontaneously. He suffered for the remainder of his life from episodic depression. He became obsessed with death, frequently suffered from dreams in which he was sentenced to death, and often attended public executions.^{4, p. 4}

Depression alternated with "instances of boisterous good spirits, even elation."^{2, p. 30} These were accompanied by "episodic debauches of compulsive sexual athleticism.... Boswell had a 'rage' of whoring until he was exhausted, much like his drinking until he was senseless."^{2, p. 36} Boswell found this hypersexuality to be inconsistent with his view of himself and often sought to impose limits on his behavior. However, he is known to have contracted gonorrhea repeatedly through impulsive sexual relations with prostitutes on numerous occasions.² He ultimately died of renal failure at the age of 55, presumably secondary to an ascending urinary tract infection.⁵

Van Liere⁵ described the scene of Boswell's death, which he ascribed to uremia. Prior to that time, and "in spite of his severe drinking bouts and his lecherism [Boswell] had always remained, as far as is known, in reasonably good health.... Boswell suffered periodic attacks of melancholia. These may have been the cause of his drinking bouts...."^{p. 109}

Tillotson et al⁶ indicate that during 1763, which Boswell spent engaged in further legal study at Utrecht, depression at times reduced him to total immobility. To cheer himself up, he embarked upon a grand tour of Europe and posed in the German courts as the Baron Boswell. From his writings at this time there is explicit evidence of hypersexuality, involving, for example, on one night, liaisons with two different prostitutes, with an effort at a third being foiled by lack of money.^{4, pp. 74-75}

Ober² has noted that Boswell's family history included considerable psychiatric illness. His brother, John Boswell, became mentally ill in his 20's, though nothing more specific is mentioned. His father's brother also apparently suffered from episodic depressions and one of Boswell's daughters suffered from paranoid ideation (consistent with a manic episode). Boswell himself described his melancholy as "hereditary in our family."^{4, p. 90} His father indicated in a letter to James that the latter's paternal grandfather had a "melancholic turn."^{4, p. 108}

There has been much speculation concerning the motives that underlay Boswell's behavior. Harris⁴ interpreted Boswell's eagerness to affiliate himself with older men in mentorships to be "a search for paternal warmth he had never known,"^{p. 4} and said Boswell took "for himself [Johnson] mentor, counselor, source, and confidant, aspects of an ideal father he had not known."^{p. 5} Harris⁴

suggested that the harshness of Scottish justice, with which Boswell as a jurist was well acquainted, was often agonizing to the writer and may have precipitated his despair and desperate behavior. In a psychoanalytic view, Ober² viewed Boswell's sexual excesses as reflections of his Oedipal conflict. Ober sought to answer the question of why would a "man of a good family, considerable education, adequate professional status, a satisfactory wife, and prominent social connections deliberately expose himself to the risk of gonorrhea?"^{p. 29} He concluded that Boswell's behavior was determined by his relationship with his father, his strict religious upbringing, and his psychosexual development.

Boswell's Own Descriptions of His Moods

In his diary, Boswell clearly acknowledges his episodic bouts of melancholia. He describes a variety of depressive symptoms. Of the first episode he writes: "...about the age of seventeen I had a very severe illness. I became very melancholy. I imagined that I was never to get rid of it. I gave myself up as devoted to misery. I entertained a most gloomy and odd way of thinking. I was much hurt at being good for nothing in life.... Many a struggle was in my mind between melancholy and mirth."^{4, p. 14} Of subsequent times he wrote: "And yet melancholy threw a cloud over my mind. I could relish nothing. I felt dispirited and languid."^{4, p. 27} On one occasion he writes: "I was so depressed that the tears run down my cheeks."⁶

In a conversation with Rousseau concerning melancholy, Boswell related, "I, for my part, suffer from it severely. And how can I be happy, I, who have done so much harm?"^{6, p. 1139} Subsequently, while again in conversation with Rousseau, he said, "It is enough, I, with my melancholy, I, who often look on myself as a despicable being, as a good for nothing creature who should make his escape from life."^{6, p. 1144}

Another feature that reflects the severity of Boswell's mood disorder is the diurnal variation he describes: "...when I open my eyes and see daylight again, a crowd of disagreeable ideas comes into my mind. I think gloomily of the variety and misery of human life. I think that it is not worth while to do anything. Everything is insipid or everything is dark.... I feel so gloomy every morning.... I believe the explanation is some physical disorder... it is with the utmost difficulty that I can get up."^{4, p. 105}

Boswell writes: "I have... a great anxiety of temper which often renders me uneasy. My grandfather had it in a very strong degree."^{4, p. 29} Though Boswell wrote extensively of his affliction, he at times referred to it as hypochondria, a term that was commonly used in the 18th century. This is particularly evident in his essays entitled *The Hypochondriack*. Jackson⁷ clarified this apparently discrepant terminology. He points out that hypochondria was used during that period to refer to depression without the psychotic features inherent in the then current usage of the term melancholy.

On the other hand, Boswell's writings reveal that

alternating with melancholy were periods of euphoria and lavish self-praise. "How easily and cleverly do I write just now.... In short, I am at present a genius: in that does my opulence consist, and not in base metal."⁴, P. 48 Following a visit to Voltaire, he wrote "what a singular being do I find myself."⁶, P. 1131 In a letter to his friend William Temple, he wrote "Sometimes I think myself good for nothing, and sometimes the finest fellow in the world.... Good Heaven! What is Boswell?"⁶, P. 1132 "It is amazing how much and how universally I have made myself admired. This is an absolute fact. I am certain of it, and with an honest pride I will rejoice in it."⁴, P. 288

In addition to this grandiosity, Boswell was given to episodes of staying up all night in order "to bring up [his] affairs and to compose [his] spirit."⁴, P. 130 He rationalized his behavior as doing penance for periods of "idleness," during which he wrote nothing.⁴, P. 57

Making a Diagnosis

In the present paper, we have focused on the psychopathological aspects of Boswell's life in order to make a psychiatric diagnosis in current terms, as an alternative to the views described above. Because a close reading of Boswell's journals reveals alterations in mood that vary between depression and moderate elation and hyperactivity, some form of bipolar disorder is suggested.

In a paper that contributed to the inclusion of cyclothymic disorder among bipolar spectrum disorders, Akiskal et al³ listed a series of characteristics that suggest that cyclothymia merges imperceptibly with forms of manic-depressive (or bipolar) illness. Included among these are: onset between the ages of 15 and 45, with a preponderant onset before age 25; recurrent, short cycles of depression and hypomania not severe enough to warrant actual diagnosis of these disorders (episodes typically lasting a few days and alternating irregularly); behavioral disturbance including promiscuity, which is ego-dystonic, apparently self-defeating and often leading to self-reproach, and marital problems; financial disasters; heightened but uneven creativity and unstable employment; episodic alcohol or drug abuse; readiness to join cults or recondite social movements; and a family history of affective (most clearly, bipolar) illness. To establish the biphasic nature of the disorder, the authors offered the following behavior patterns: hypersomnia alternating with decreased need for sleep; grandiose over-confidence alternating with self-doubt; marked unevenness in quantity and quality of work, along with unusual self-imposed working hours; periods of apathy alternating with heightened creativity; and an alternating pattern of alcohol or drug abuse.

In a subsequent review of milder bipolar disorders, Akiskal⁸ described cyclothymic disorder as a temperamental disorder that is intermittent and lifelong. In this disorder, the mood change is often subtle, although behavioral and interpersonal disturbance are in evidence. In the individual's usual state, affective symptoms do not

crystallize into discrete episodes. Typically there are short cycles of depression and hypomania that last a few days, occur irregularly, and often reverse abruptly.

Having listed these empirical diagnostic criteria, it should be apparent to the reader that the events and moods described by Boswell and his biographers justify a diagnosis of cyclothymic disorder. There is substantial evidence that Boswell suffered from cyclic alterations in mood, accompanied by behavior that ultimately appears to have contributed directly to his death. It should also be emphasized that the symptoms and behaviors described were enduring ones. The traits that first appeared when Boswell was 17 persisted throughout his life.

Relevant to the question of psychopathology in Boswell is a study by Andreason and Canter,⁹ in which psychiatric symptomatology and diagnosis were compared between 15 writers of high creative stature and a control group of 15 individuals outside the creative arts. The authors concluded that the writers suffered from significant psychopathology, which might be seen as incompatible with the degree of success they had achieved. Ten writers met criteria for affective disorder, compared with only two of the controls. Nine met criteria for cyclothymic personality, while only two of the controls did. Six writers were diagnosed as alcoholic, compared with only one of the controls. Of the subtypes of cyclothymic disorder, the most common is the predominantly depressed group,⁸ which best characterizes Boswell's illness also.

In a recent article, Andreason¹⁰ reported findings very similar to those of her earlier study with Canter.⁹ She contrasted rates of mental illness in 30 creative writers, 30 matched controls, and first-degree relatives of both groups. Among the writers the prevalence of affective disorder was 80%, nearly three times the rate of the control sample. Nearly half of the affective disorders among writers were bipolar disorders. Similarly, the prevalence of affective disorder among the relatives of writers was much higher than among control subjects' relatives. Comparison of the association of creativity and mental illness among probands and family members highlighted the interplay between these phenomena, a finding that is relevant to a consideration of Boswell's literary life and psychopathology.

It is unclear whether Boswell's psychiatric illness enhanced his literary creativity. However, it is reasonable to conclude that there is some relationship between his apparent cyclothymic disorder and his creativity. Andreason and Canter⁹ suggested that something unhealthy in the literary climate of the 20th century contributed to the development of affective disorder in modern writers. It is not possible to make a historical diagnosis with the same degree of confidence as is possible for contemporary figures. However, the idea that James Boswell suffered from a variant of bipolar disorder is well supported by historical evidence, including that reflected in his voluminous writings. This argues for an enduring associ-

ation between literary creativity and affective disorder, rather than something unique to the present century. A review of the lives of other accomplished writers may help clarify the relationship between affective disorder and creativity.

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50 Years Ago

From the *Journal of the Connecticut State Medical Society* April 1939

AT THE HALF CENTURY MARK

The principles of aseptic surgery were announced to a skeptical medical profession a little more than seventy years ago. The memory of the carbolic acid spray then described remains as a relic of medical progress. That one of our own Connecticut physicians is still actively engaged in the practice of medicine and recounts from personal observation this epic transition in surgery, we feel is a notable fact. To illustrate the state of surgical technique when he was still a medical student, this man relates the following incident which occurred while he was administering an anesthetic. The Chief Surgeon of the old New York Hospital found it a convenience to slip the needle threaded with linen through the coat of his assistant in order to have it readily available for approximating his tissues. Somewhat irritated on one occasion, he reached for the needle and snorted, "Sir, it seems to me you are most valuable as a pin cushion."

Born in the Connecticut town of Essex, October 29th, 1859, this boy engaged the attention of Dr. Charles Hubbard, who recognizing his potential ability as a practitioner, volunteered to act as his preceptor without fee. Thus Elias Pratt began the study of medicine. He has practiced in the city of Torrington for more than fifty years. His regard for the signal service rendered by Dr. Hubbard is given as his reason for not returning to his native village to practice medicine. His ancestry is traced back to John Pratt who founded the blacksmith shop in Essex in 1678. An unbroken line of successive generations has continued this enterprise up to the present day. High school education was secured in Middletown and Hartford. Because of family finances it seemed impossible for him to secure a college education. Securing work in Ivoryton in an ivory piano key factory, he recited to

Dr. Hubbard two evenings a week passages from Quain's Anatomy and discussed observations which he had made from the study of a borrowed skeleton.

Stimulated by his contact with Dr. Hubbard he sought more information at the College of Physicians and Surgeons of Columbia University in New York City where he matriculated in 1884. The school was then situated at 23rd street and Park Avenue and the terms began in October and ended in May. After graduating in 1887 he interned for a period of eighteen months at the Blackwell Island Hospital. When he began his service, iodine for preparation of the patients' skin was first being substituted for the carbolic acid spray previously mentioned. He was married in 1890 to Maria Blake and has one son. From 1889 to 1891 he was Representative from Torrington to the Connecticut Legislature. While in the House he served on the Committee of Public Health and Safety. He was elected president of the Connecticut State Medical Society in 1923. He also served two terms as president of the Litchfield County Medical Association. His selection as president for a second term was made in order that he might be prominent in the celebration of the one hundred fiftieth anniversary of the founding of that society.

When asked his opinion as regarding social medicine, Dr. Pratt replied, "I do not favor any form of government control of medicine; however, under certain circumstances I think the government should provide funds for medical care, but the control and management of these operations should remain in the hands of the physician."

—Editorial by Francis A. Sutherland, M.D.

Formaldehyde

AMA COUNCIL ON SCIENTIFIC AFFAIRS

In response to Resolution 195 (A-87), the medical literature on the adverse health effects of formaldehyde was reviewed, and the potential cancer risk to anatomists and other related health professionals from exposure to the chemical is described. Though the evidence in humans is limited and controversial, both the Environmental Protection Agency and the Occupational Safety and Health Administration, in their consideration of available epidemiologic and toxicological studies, now regard formaldehyde as a possible human carcinogen and will regulate it accordingly.

IN 1985, the American Medical Association adopted Council on Scientific Affairs Report D (A-85),¹ which primarily discussed formaldehyde in manufactured housing. Report D included a general review of the adverse health effects of formaldehyde on animals and humans reported in the literature through 1985. Report D concluded that formaldehyde acts on humans principally as an irritant to the eyes and upper respiratory system, impairs the mucociliary mechanism and flow of mucus, and can produce allergic contact dermatitis when aqueous formaldehyde comes into contact with the skin. Formaldehyde is known to cause nasal tumors in some rodents, but it is not proved conclusively to be responsible for these or other tumors in humans.

Since around 1981, events have altered many opinions about the effects of formaldehyde on humans and, consequently, its regulation.² In the aftermath of public hearings conducted by the Occupational Safety and Health Administration (OSHA) prior to the proposed final rule, 1,400 exhibits and 30,000 pages of testimony and comments were condensed into 122 pages of sum-

mary and conclusions in the Preamble to the Final Rule,³ which, along with the Final Rule,⁴ represents a useful source of information on this subject.

Based on "limited" epidemiologic data and "sufficient" evidence from standard chronic toxicity, rodent carcinogenicity, and other experimental studies, certain regulatory agencies regard formaldehyde as a possible human carcinogen. This is a controversial opinion in the view of many industry and academic scientists who have interpreted the same data. The emphasis of this report, therefore, will be on review of the limited human evidence of carcinogenicity that has led to the regulatory decision.

Adverse Health Effects

Inhaled formaldehyde primarily affects the airways; the severity and extent of physiological response depend on its concentration in the air. As the concentration increases, cell proliferation and cell death (ie, cell turnover) increase and, as in animals, there is a dose-dependent decrease in mucociliary activity.⁵ For the most part, the relatively low threshold of response and the disagreeable, irritating odor of formaldehyde prevent one from breathing intolerable amounts of the gas. In rare massive acute exposures, victims have suffered pulmonary edema and even death. Relatively low concentrations have provoked or exacerbated asthmatic symptoms in some individuals. It has been suggested⁶ that long-term inhalation of formaldehyde may trigger classic IgE-mediated nasal allergy in atopic individuals.

In the first formaldehyde dose-response investigation of acute symptoms *and* pulmonary function in humans under carefully controlled conditions, 19 healthy adult nonsmokers were exposed to 0.0 to 3.0 ppm of formaldehyde for three hours in an environmental chamber.⁷

From the Council on Scientific Affairs, American Medical Association, Chicago.

This report was submitted to the House of Delegates of the American Medical Association at the June 1988 Annual Meeting as Council on Scientific Affairs Report E. The action of this report was adopted as amended.

This report is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all of the facts and circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and patterns of practice evolve. This report reflects the views of scientific literature as of June 1988.

Members of the Council on Scientific Affairs include the following: Scott Bernstein, Champaign, Ill, Medical School Representative; George M. Bohigian, MD, St. Louis, Chairman; Yank D. Cobel, MD, Gainesville, Fla; E. Harvey Estes, Jr, MD, Durham, NC; Ira R. Freidlander, MD, Chicago, Resident Representative; William R. Kennedy, MD, Minneapolis; Patricia Joy Numann, MD, Syracuse, NY; William C. Scott, MD, Tucson, Vice-Chairman; Joseph H. Skom, MD, Chicago; Richard M. Steinhilber, MD, Cleveland; Jack P. Strong, MD, New Orleans; Henry N. Wagner, Jr, MD, Baltimore; William R. Hendee, PhD, Secretary; William T. McGivney, PhD, Assistant Secretary; and R.H. Wheeler, MS, Staff Author.

These concentrations were considered typical of industrial, commercial, and domestic exposures. The degree of odor perception and eye irritation was significantly related to dose, although there was a wide variation in threshold response; nasal airway resistance did not increase until the formaldehyde level reached 3.0 ppm. No significant decrease in pulmonary function or increase in bronchial reactivity to methacholine occurred either at 0.5 to 3.0 ppm while subjects were at rest or at 2.0 ppm during exercise.

In another study, 15 healthy nonsmokers were subjected to a controlled environment of 2.0 ppm of formaldehyde to demonstrate possible changes in respiratory effects. Neither acute nor delayed changes in lung function were noted.⁸ When mildly asthmatic volunteers were exposed similarly, both at rest and after moderate exercise, they too did not develop significant acute or delayed bronchoconstriction; however, brief formaldehyde exposures could cause signs of nonspecific hyper-responsiveness in their airways.⁹

Svenberg et al¹⁰ at the Chemical Industry Institute of Toxicology were the first to note that formaldehyde induces squamous cell carcinoma of the nasal mucosa in rats. Their findings were corroborated by other investigators.¹¹⁻¹³ In brief, long-term bioassays of two strains of male and female rats and one strain of mice developed benign and malignant tumors of the same cell types and locations. Monkeys exposed to formaldehyde resembled rats by developing squamous cell metaplasia and basal cell hyperplasia. Experiments with hamsters were inconclusive.^{3,4} Attempts have been made during the past few years to translate the findings from animals to man; however, there are physiological and metabolic differences between species and even among various strains of mammals that make translation between other species and man extremely difficult and controversial.

Epidemiologic evidence has been contradictory. The annual incidence of human nasal cancer is about eight cases per million men in the United States; this rare form of cancer is difficult to find among formaldehyde-exposed workers, who should be most susceptible. These workers experience a number of "nonspecific mucosal abnormalities" (eg, edema, erythema, and fissuring), but nasal polyps are not especially common.¹⁴ One occupationally related case of nasal cancer, including bilateral polyps, was reported in 1983.¹⁵ Shortly thereafter, two occurrences of nasal polyps prompted an examination of exfoliated nasal cells in 80 workers in a phenol/formaldehyde production plant. A statistically significant prevalence of mucosal irritation (ie, erythema, edema, and fissures) was present, especially in those with more recent exposures. Atypical squamous metaplasia, present in five members of the exposed group and in ten control subjects, seemed to be related to age rather than to formaldehyde exposure; in addition, after age and smoking were taken into account, the negative association between formaldehyde and metaplasia persisted.

In a case-control study¹⁶ of 57 cases of respiratory lung cancer among Finnish workers in the wood and formaldehyde/glue manufacturing industries, no significant relationship was found. The study, however, was capable of detecting only large excesses in risk because of its low power and inadequate follow-up.

Population-based case-control studies^{17,18} of sinonasal and pharyngeal cancers (identified from a tumor registry) likewise were limited by size and could not detect small increases in risk. No association was found when the assessment of formaldehyde exposure was linked to the job.

A National Institute for Occupational Safety and Health investigation of 256 deaths in three garment industry plants¹⁹ (the initial phase of a two-part series of studies on this industry) revealed no nasal cancer deaths, and the mortality from respiratory cancer was slightly less than expected. There was, however, a statistically significant increase in proportionate mortality for malignant neoplasms of the biliary ducts and liver (four), other lymphatic and hematopoietic sites (four), and the buccal cavity (three). The proportionate cancer mortality ratios for other lymphatic and hematopoietic sites and for the buccal cavity were still significantly elevated when the data were reanalyzed. The small number of deaths and the "lack of consistency with other studies" make these findings inconclusive.

A retrospective cohort mortality study (the second phase) by the National Institute for Occupational Safety and Health²⁰ of 11,030 workers in plants that produced permanent-press garments found statistically significant excesses in deaths from cancers of the buccal cavity (of the four females who died, two had tumors of the parotid gland, one of the oral mucosa [in a snuff user], and one of the soft palate), tonsils, and connective tissue. No deaths occurred from nasal cancer, but an apparent increase in mortality also was observed from lung, tracheal, and bronchial neoplasms, bronchitis, and leukemia as well as a decrease from brain tumors. Despite the small number of cases, the authors believe that the excess mortalities from buccal cavity cancers, leukemia, and lymphopoietic neoplasms are related to formaldehyde. Independent analysis of the data by the Environmental Protection Agency (EPA) showed that the trend between deaths from buccal cavity cancer and exposure duration was statistically significant.

The latest mortality study by Blair et al²¹ of the National Cancer Institute included the largest cohort of any formaldehyde study and involved 26,561 workers employed in ten formaldehyde-producing or -using plants; more than 80% of the cohort were white men. Mortality from all causes was about that expected among white men; the slight excesses of Hodgkin's disease and cancers of the lung and prostate were not consistent with duration or level of exposure. Deaths from leukemia and brain cancer were not excessive, in contrast to earlier reports of excesses among anatomists, embalmers, and

pathologists. Reduced numbers of deaths from deficits for buccal cavity and pharyngeal cancers contrasted with the elevated mortality from oropharyngeal and nasopharyngeal cancers, but the risk for the latter did not always increase with an increase in exposure level. Lack of a dose-response relationship for lung and nasopharyngeal cancer deaths led the authors to conclude that the evidence was inadequate to support an association between formaldehyde exposure (which ranged from a trace to more than 2.0 ppm) and cancer. This apparent lack may have been due to misclassification, recall bias, and inadequate duration of exposure.

The study by Blair et al²¹ has been criticized on a number of counts. Some critics thought that the investigators overemphasized the need for a dose-response relationship. The National Cancer Institute reexamined the cases of nasopharyngeal and oropharyngeal cancers and found that these had occurred in plants that produced dusty formaldehyde resin-molding compounds, thus raising the question about the significance of particulate matter as a cofactor.²² Representatives of one of the companies in the study disagreed with the conclusions of the National Cancer Institute because (1) the relationship between formaldehyde, particulate matter, and nasopharyngeal cancer was inconsistent (no other excesses of this type of cancer were found in other plants); (2) the definition of “particulate” was too broad, and the amount and the type were not specified; (3) some of the decedents in one plant did not receive the highest or the longest duration of formaldehyde-particulate exposures; and (4) direct instead of indirect standardization across exposure groups would have minimized “problematic interpretations.”²³

Anatomists and Persons in Related Professions

The pulmonary function of white male morticians in West Virginia was found to compare favorably with that of residential populations in Oregon and Michigan. Relatively high exposures to formaldehyde were not associated with chronic bronchitis or pulmonary function deficits, which suggests that the long-term, intermittent exposures to low levels of formaldehyde (at least a time-weighted average not exceeding 1.2 ppm or a half-hour peak of 2.1 ppm) will have no “meaningful chronic effect” on respiratory health.²⁴ A similar conclusion was reached by another group of researchers.²⁵ These findings contradict the results of another study;²⁶ the latter, however, was criticized for, among other factors, its lack of a control group.

Seventy-six female histology technicians who were exposed daily to formaldehyde (ambient levels, 0.2 to 1.9 ppm) (as well as to xylene, chloroform, and toluene) were evaluated for various neurobehavioral symptoms.²⁷ The results should be viewed as preliminary because of several flaws in the study.

When the causes of death among male pathologists who belong to the American Association of Pathologists

and Bacteriologists and the American Society for Experimental Pathology were compared with the causes of death among psychiatrists, no significant excesses for neoplasms of the liver and lymphomas were noted among American Society for Experimental Pathology members and no significant excesses from esophageal, pancreatic, brain, and small intestine neoplasms or lymphomas and multiple myelomas were noted among American Association of Pathologists and Bacteriologists members. However, a statistically significant increase in proportionate mortality ratios from neoplasms of the hypopharynx was found when the pathology groups were combined and compared with other nonexposed physicians.²⁸

A study of 2,079 pathologists belonging to either the Royal College of Pathologists or the Pathological Society of Great Britain from 1955 to 1973 disclosed significantly high standardized mortality ratios for lymphopoeitic cancer, especially lymphatic and hematopoietic diseases other than Hodgkin's disease or leukemia. Also, the 154 deaths from all causes and from all neoplastic diseases among 12,944 laboratory technicians were not statistically significant.²⁹

From a cohort of 2,307 male and 413 female members of the Royal College of Pathologists, 126 deaths—due to accidents, poisoning, violence, and drug-related suicide—from 1974 to 1980 were identified as being in excess of the expected number in the general population but typical in number for medical practitioners. Brain (astrocytoma/glioma cell type) and bladder tumors were in excess for the men (six observed vs less than two expected), which may have been due to organic solvents; deaths from lymphatic and hematopoietic neoplasms were in excess only for women. There were no nasal tumors, and the standardized mortality ratio for lung cancer was well below 1.0.³⁰

In a study comparing the causes of death among 1,477 Ontario morticians with those for Ontario white males, standardized mortality ratios, especially for leukemias/aleukemias and brain cancers, were not significantly increased. When the same mortician deaths were compared with US white males, the standardized mortality ratios increased with time from first exposure for brain and lymphopoeitic cancers and for leukemia/aleukemia. No increase in risk of death from cancer at sites of contact with formaldehyde was evident. Only deaths from cirrhosis of the liver and chronic rheumatic heart disease were significantly in excess.³¹

A retrospective cohort study of 2,317 male members of the American Association of Anatomists (who joined the organization between 1888 and 1969) vs US white males indicated that standardized mortality ratios were 0.3 for lung cancer, 1.5 for leukemia (limited to the myeloid type), and 2.7 for brain cancer. Compared with male members of the American Psychiatric Association, these same anatomists' standardized mortality ratios were 0.5 for lung cancer and 6.0 for brain cancer. Each of the ten brain deaths was due to neuroglial cell tumors

(either astrocytoma or glioblastoma).³²

An unpublished, retrospective, follow-up study³² of 2,239 anatomists from the American Association of Anatomists vs US white males disclosed that brain cancers (ie, astrocytoma/glioblastoma cell type) and leukemias (50% were myeloid) were in excess; there were, however, fewer than the expected number of deaths from all causes and from lung cancer.

A proportionate mortality ratio study of 1,132 funeral directors and embalmers licensed in New York, while lacking specific personal exposure data, found a significant increase in mortality from skin and colon cancers and lesser increases from tumors of the buccal cavity and pharynx, the digestive system, the liver, the pancreas, the lung, the brain and central nervous system, the kidney, and the lymphatic/hematopoietic system. There were, however, no nasal cavity or sinus neoplasms.³³

In like manner,³⁴ 1,050 embalmers in California were surveyed. No nasal cavity or sinus neoplasms were reported; there was a significant mortality increase from leukemia and tumors of the brain and prostate but statistically insignificant increases in deaths from cancers of the lymphatic/hematopoietic system and the buccal cavity and pharynx and slight decreases in lung cancer mortality.

Magnitude of Formaldehyde Exposure and Risk Among Anatomists and Persons in Related Professions

One of the earliest surveys of environmental levels of formaldehyde in funeral homes was an evaluation of ventilation systems (essentially wall-mounted exhaust fans) in six funeral homes.³⁵ Ambient levels of formaldehyde ranged from 0.75 to 2.50 ppm (without ventilation) to 0.25 to 1.39 ppm (with ventilation). The author did not attempt to determine concentrations at the breathing zone; thus, the extent of personal exposure is unknown.

Another survey of seven funeral homes in 1980, involving both area and personal sampling, determined that embalmers were exposed to 0.1 to 0.4 ppm of formaldehyde when working with intact bodies and 0.5 to 1.2 ppm of formaldehyde when working with autopsied bodies.³⁶

Personal and ambient air samples during class sessions in eight gross anatomy laboratories of a major medical school over a 12-week period were evaluated.³⁷ Only 11% of the ambient air samples exceeded 1.0 ppm whereas 44% of the personal samples were above 1.0 ppm. Most (62%) of the daily mean exposures varied between 1.0 and 2.0 ppm, and half were between 0.6 and 1.0 ppm; the lowest was 0.3 ppm and the highest was 2.63 ppm.

In one medical center autopsy service, weekly time-weighted average exposures for pathologists, residents, and technicians were between 0.61 and 1.32 ppm. On the average, the time-weighted average exposures were similar for all personnel in the study; when work patterns were examined, however, technicians encountered the lowest levels over a long period whereas physicians

involved in tissue sectioning and examining, for example, were exposed to the highest levels but for the shortest duration.³⁸

In 1984, the OSHA and the EPA estimated that the size of this potentially exposed group—ie, pathologists, funeral service workers, and medical, dental, and nursing students—to be approximately 400,000 persons. Excess lifetime risk of cancer for individual members of this group ranged from less than one to almost 2,000 additional cases per 100,000 persons (Table 1).

Table 1.—Estimates of Exposed Populations, Personal Exposures, and Lifetime Additional Cancer Risk^{39, 40}

Exposed Group	Group Size, No.	Exposure Level, ppm	Excess Risk, No. of Cases per 100 000 Persons
Funeral service workers	55 000	1.0-3.0	1938
Pathologists	12 000	>3.0	1367
Students			
Medical	74 900	0.4	<1
Dental	21 500	0.4	<1
Nursing	245 000	0.4	<1
College	2 903 000	0.4	<1-9.6
High School	3 384 000	0.4	<1-1
Teachers			
College/university	108 600	0.4	<1-7.6
High school	38 600	0.4	<1-1

This is a substantial population, and it becomes even more sizable if the less identifiable college and high school students and their teachers are included. Unfortunately, very little data are available concerning the actual concentration or duration of exposure; therefore, the extent of risk can only be estimated. Again, the OSHA and the EPA estimate exposures ranging from a low of 0.4 ppm to greater than 3.0 ppm. According to a Dec 12, 1987, report by Fischbein,⁴¹ the OSHA estimated about 30,000 funeral service workers would be exposed above the new 2.0 ppm short-term limit but below the 0.5 ppm action level.

Recent figures on the number of exposed workers and their estimated exposures, from Tables 5 and 8 of the Preamble,³ are set out in Table 2.

Table 2.—Estimates of Exposed Populations, Personal Exposures, and Cancers Avoided at the 1.0 ppm Permissible Exposure Limit

Exposed Group	Group Size, No.	Exposure Level, ppm	No. of Fewer Cancers
Funeral service workers	30 000	0.1-0.5	...
Laboratories (ie, pathology, histology, and gross anatomy)	36 661*	...	...
	24 441	0.1-0.5	...
	5951	0.5-1.0	...
	6269	>1.0	4.8-28.9
Hemodialysis	31 500	0.1-0.5	...
Biology instruction	28 950	0.1-0.5	...
Veterinary anatomy	38	0.1-0.5	...

*Total number of persons exposed.

Estimated costs of compliance and the numbers of cancers and respiratory and dermal disorders avoided also are tabulated in the Preamble in Tables 6, 8, and 9, respectively. Depending on the choice of risk-estimation model, the new standard is expected to reduce cancer risk by as much as 67% to 96%. On the other hand, the EPA's linear multistage cancer risk model, which is questionable and unsupported by most statisticians, predicts that the upperbound estimation of risk of developing cancer at the revised "ambient exposure levels" over a 70-year lifetime will be 1.3 cases per 100,000. Other federal agencies are expected to use the EPA's assessment for decision making.⁴²

Regulatory Status

On April 16, 1987, the EPA issued its health risk assessment of formaldehyde and now classifies it as a "probable human carcinogen" (group B1) based on "limited evidence" from nine of the 28 epidemiologic studies they reviewed. Three of these nine studies (ie, 1986 and 1987 studies by Blair et al^{21,23} and a 1986 study by Stayner et al²⁰) showed a statistically significant association between formaldehyde exposure and respiratory site-specific cancers (lung and nasopharyngeal area, buccal cavity, and oropharynx). Other supportive evidence came from structure-activity correlations and short-term tests on DNA. Twenty-five epidemiologic studies that the EPA reviewed earlier lacked sufficient power for determining risk, and the populations in each study were "undoubtedly exposed to other chemicals" besides formaldehyde that could have contributed to cancer risk. Nevertheless, the EPA, compelled by law to issue environmental health standards even in the absence of conclusive safety assessment data, believed that six of the 25 studies were persuasive enough to furnish corroborative evidence for purposes of regulation.

The EPA ended its evaluation of occupational exposure risk on Feb 18, 1986, in deference to the OSHA's jurisdiction in this matter. The OSHA has claimed that the EPA's and the International Agency for Research on Cancer's decisions, made known only after its record was closed, did not influence its own decision that formaldehyde is a "probable carcinogen."

Since 1981, labor unions and others have been pressuring the OSHA to lower the occupational standard for formaldehyde exposure in the workplace. After repeated delays, the Agency was ordered on Oct 15, 1987, by the US Court of Appeals for the district of Columbia to issue a final rule by Nov 21, 1987. Failure to comply with the court's request would have forced the OSHA to pay court costs and attorney's fees.⁴³ The OSHA finally issued the new standard (which will be phased in over the next year) to cover *all* industries that are included under the Occupational Safety and Health Act. Workplace exposures must not exceed a time-weighted average of 1.0 ppm over the eight-hour workday; a short-term exposure limit that shall not exceed 15 minutes will allow personal exposures to reach 2.0 ppm. Moreover, employees must be monitored, and they must be provided training and medical surveillance whenever the 0.5 ppm action level over an eight-hour period occurs. In addition, employers will be required to provide workers with personal protective equipment, emergency planning measures, and hazard information.

The OSHA expects employers to control personal exposures primarily by engineering and administrative means; it will allow the use of personal protective equipment only in special situations as defined by law.

The new standard should have become effective on Feb 2, 1988, sixty days after its publication (Dec 4, 1987) in

the *Federal Register*. However, lawsuits filed by the industry (as represented by the Formaldehyde Institute) and the trade unions on Dec 4, 1987, have now blocked its promulgation. Industry wants less stringency in the standard, the unions want more. The Formaldehyde Institute also has petitioned for a judicial review of the requirements for labeling, arguing that a cancer warning will have to appear on all particleboard and permanent-press fabric.⁴⁴

The College of American Pathologists, in statements to the OSHA (Aug 13, 1985) and the Department of Labor (March 5, 1986), recommended that formaldehyde levels in the laboratory be kept as low as possible with good ventilation—no higher than 1.0 ppm, time-weighted average per eight-hour workday. The College was concerned that a regulation that was too stringent would be impossible to monitor or enforce; formaldehyde could no longer be used in histological procedures for which there is no acceptable substitute, and the costs of compliance would lead to further escalation in health care expenses.

Monitoring and Control Strategies

A variety of environmental and personal monitoring devices are commercially available. Before using any of them, however, one should be aware of their limitations. Engineering controls come under the purview of the professional industrial hygienist and ventilation engineer, who should be competent to survey the work environment, to design an adequate ventilation system, and to monitor and maintain exposure levels to meet the OSHA standard.

The OSHA has singled out certain laboratories that use formaldehyde—namely, histology, pathology, and anatomy laboratories—that will not be exempted under the provisions of the Toxic Substances in Laboratories standard. As a consequence, histology and pathology laboratories must have engineering controls (specifically, hoods) and must adopt work practices to lower short-term exposure levels. Mortuaries will be required to have local exhaust ventilation.

The latest revision of Title 29 of the Federal Code of Regulations (29 CFR 1910 [July 1, 1987]) pertaining to occupational safety and health contains no express standards for ventilation systems or other mechanisms to control ambient levels of formaldehyde in hospitals, pathology laboratories, and the like. Discussions with representatives of these institutions and others disclosed that they were unaware of any changes since July 1987. Unless specific standards are established, formaldehyde users (or generators) must rely on guidelines that may be recommended by such organizations as the National Institute for Occupational Safety and Health, the Academy of American Pathologists, the American Conference of Governmental Industrial Hygienists, the American Hospital Association, the American Industrial Hygiene Association, and the American Society for

Heating, Refrigeration, and Air Conditioning (ASHRAE). For the time being, the Final Rule regarding engineering control and work practices states:

There are two distinct types of ventilation. Local Exhaust: . . . designed to capture contaminants as near to the source of generation as possible . . . the direction of contaminant flow must always be toward the local exhaust system inlet and away from [the worker]. General (Mechanical): General dilution ventilation involves continuous introduction of fresh air into the workroom to mix with the contaminated air and lower [the] breathing zone concentration of formaldehyde. Effectiveness depends on the number of air changes per hour. Where devices emitting formaldehyde are spread out over a large area, general dilution ventilation may be the only practical method of control. "Work Practices . . . and administrative procedures are an important part of a control system. If . . . asked to perform a task in a certain manner to limit [personal] exposure to formaldehyde, it is extremely important that [the worker] follow these procedures." ASHRAE is currently revising its 1981 standard, "Ventilation for Acceptable Indoor Air Quality" (ASHRAE 62-1981). Both the current and draft standard offer recommendations on make-up air in hospitals, nursing and convalescent homes (including medical procedure, operating and autopsy rooms), and educational laboratories. Presumably the new ASHRAE standard will be more specific regarding formaldehyde in these facilities in light of the OSHA standard, but there presently is no assurance of how extensive the changes will be.

Summary and Conclusions

The US regulatory agencies—the EPA and the OSHA—believe that human and animal data are now adequate to regard formaldehyde as a probable human carcinogen. The controversy surrounding this issue since 1981, however, shows no signs of relenting, and continued scientific study is needed.

Many worker exposures to formaldehyde allegedly are already at or below the proposed permissible exposure limit (as well as the short-term exposure limit), and, therefore, the new limits are attainable. Thus, most employers should be able to maintain a reasonably safe working environment until the matter is resolved. Implementation of the appropriate engineering controls and work practices, rule or not, will be best left to the professional competence of the occupational physician, industrial hygienist, and ventilation engineer.

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Drugs for Parkinsonism

THE MEDICAL LETTER

Patients with Parkinson's disease have a deficiency of the neurotransmitter dopamine, a catecholamine. Dopamine itself cannot be used to treat the disease because it does not cross the blood-brain barrier, but its metabolic precursor, levodopa, does cross into the brain and is converted to dopamine by a decarboxylase present both in the brain and in the intestinal tract (JM Cedarbaum, *Clin Pharmacokinet*, 13:141, 1987).

LEVODOPA—Levodopa relieves many of the symptoms of parkinsonism, and its use has improved both the quality and duration of life in patients with this disease. Since levodopa is rapidly decarboxylated in the intestinal tract, a large amount must be taken orally for a small amount to penetrate the blood-brain barrier. However, large amounts of dopamine formed by peripheral decarboxylation of levodopa can cause anorexia, nausea, vomiting and cardiac arrhythmias; levodopa, therefore, is now rarely used alone.

LEVODOPA AND CARBIDOPA—*Sinemet*, a combination of levodopa with carbidopa, a peripheral decarboxylase inhibitor, is the most effective drug available in the USA for treatment of Parkinson's disease. Carbidopa prevents many of the adverse effects caused by dopamine after peripheral decarboxylation of levodopa. *Sinemet* is available in three preparations, 10:100 (mg carbidopa:mg levodopa), 25:100, and 25:250. The usual dosage range is 300 to 1000 mg of levodopa; some patients may require up to 2000 mg. Relatively complete inhibition of peripheral decarboxylase requires at least 75 mg per day of carbidopa; some patients require much larger doses.

LIMITATIONS—Levodopa is most effective in the first two to five years of treatment. Later, as the disease progresses, the benefit from each dose becomes shorter (the "wearing-off" effect), and some patients have sudden fluctuations between mobility and immobility (the "on-off phenomenon"). Some neurologists believe that levodopa may have a time limit on its effectiveness and therefore should be reserved for severe forms of the disease; others start the drug early and try to keep the

dosage low (RC Duvoisin, *Ann Neurol*, 22:2, 1987). Dietary amino acids can decrease the effectiveness of levodopa by competing with the drug for absorption from the intestine and for transport into the brain (T Eriksson et al, *Neurology*, 38:1245, Aug 1988).

ADVERSE EFFECTS—The most disturbing long-term effects of levodopa are frequent abnormal involuntary movements (dyskinesias, dystonias), which usually are dose-related. The drug may also cause unpleasant dreams, hallucinations and other mental changes, especially in patients with some pre-existing dementia (HL Klawans, *J Neural Transm*, 27 suppl:117, 1988). Temporary withdrawal of the drug (a "drug holiday") for four to 14 days may cause a dangerous recrudescence of parkinsonian symptoms and should be reserved for patients with intolerable adverse effects (R Mayeux et al, *N Engl J Med*, 313:724, 1985; RG Feldman, CG Goetz et al, *N Engl J Med*, 314:851, 1986).

BROMOCRIPTINE—Bromocriptine (*Parlodel*) is a dopamine agonist that can relieve akinesia, rigidity and tremor in many patients with Parkinson's disease. It has less antiparkinson effect than levodopa when used alone, but may cause fewer abnormal involuntary movements and has a longer duration of action. Nausea and orthostatic hypotension may occur early in treatment, but can be avoided by increasing the dosage slowly. Domperidone (*Motilium*), a peripheral dopamine antagonist available in Canada but not in the USA, can apparently block nausea caused by bromocriptine (JD Parkes, *Clin Neuropharmacol*, 9:517, 1986; MC Champion et al, *Can Med Assoc J*, 135:457, 1986). The main disadvantage of bromocriptine, especially in high doses (more than 30 mg/day), is the frequent occurrence of mental disturbances, including nightmares, mild agitation, hallucinations and paranoid delusions, especially in elderly patients. Angina pectoris, impotence, erythema and edema of the lower extremities and Raynaud-like digital spasms occur rarely. Retroperitoneal fibrosis and contractures of the extremities have been reported (JV Bowler et al, *Lancet* 2:466, 1988; NP Quinn et al, *Clin Neuropharmacol*, 11:268, 1988).

The best results with bromocriptine have occurred

early in treatment when the drug was given concurrently with *Sinemet*. Low doses of bromocriptine (less than 30 mg/day) combined with *Sinemet* can ameliorate the "wearing off" and "on-off" effects after prolonged use of levodopa (UK Rinne, *Neurology*, 37:826, 1987). Also, when bromocriptine is given concurrently, levodopa can be given in lower doses (less than 1000 mg/day), causing fewer dyskinesias and dystonias. However, the toxicity of levodopa and bromocriptine, particularly their mental effects, may be additive.

Some clinicians start with a test dose of 1.25 mg of bromocriptine at bedtime for several days to rule out extreme sensitivity to the drug's hypotensive effect, and then increase the dose gradually about every week; the usual dosage range is 10 to 40 mg daily. As the dose of bromocriptine is increased, levodopa dosage may have to be decreased to prevent additional adverse effects.

ANTICHOLINERGICS—In Parkinson's disease, the decreased activity of dopamine makes the excitatory effects of acetylcholine more prominent. Before levodopa, anticholinergic agents were used alone to treat Parkinson's disease, and they are still useful in some patients, especially for tremor. Although not as effective as levodopa or bromocriptine, they may have an additive therapeutic effect at any stage of the disease when taken concurrently. Adverse effects of anticholinergic drugs include dry mouth, constipation, urinary retention, aggravation of glaucoma, impaired memory, confusion and hallucinations. Anticholinergics available in the USA include trihexyphenidyl (*Artane*; and others), benztropine (*Cogentin*; and others), procyclidine (*Kemadrin*), biperiden (*Akineton*) and ethopropazine (*Parsidol*—a phenothiazine with anticholinergic activity). Antihistamines such as diphenhydramine (*Benadryl*; and others) also have anticholinergic effects and are occasionally useful for patients who cannot tolerate the more potent anticholinergics.

AMANTADINE—Amantadine (*Symmetrel*; and others), an antiviral drug found by chance to be useful in parkinsonism, may increase release of dopamine in the brain. It is generally used alone, in a dosage of 100 mg bid or tid early in the disease or as an adjunct in later stages. Some patients may not respond to amantadine, but the drug should be taken for about two weeks before assuming it is ineffective. Confusion and hallucinations, ankle edema and livedo reticularis can occur. The drug is not metabolized, but is excreted in urine; dosage must be decreased for patients with renal dysfunction. Amantadine and anticholinergics used concurrently must be given cautiously because their adverse effects on mental function may be additive.

SELEGILINE (Deprenyl)—Selegiline (*Eldepryl*—Somerset) is a new drug for Parkinson's disease now available in the USA under the new FDA policy for "promising" investigational drugs. Practitioners can obtain the drug from the manufacturer (201-586-2310); patients are enrolled in an approved protocol and must pay for the drug. A selective monoamine oxidase (MAO)-type B inhibitor formerly known as deprenyl, selegiline

is used concurrently with levodopa; it prevents catabolism of dopamine in the brain and is especially useful in patients with "wearing off" effects (AN Lieberman et al, *NY State J Med*, 87:646, 1987). MAO-B inhibitors, unlike MAO-A inhibitors used for treatment of depression, do not cause hypertension after digestion of tyramine-rich foods or beverages.

In animals, selegiline prevents selective destruction of neurons in the substantia nigra by the neurotoxin N-methyl-4-phenyl-1,2,3,6-tetrahydropyridine (MPTP). In one retrospective study, patients with parkinsonism who took selegiline and levodopa lived longer than patients who took levodopa alone (W Birkmayer et al, *J Neural Transm*, 64:113, 1985). A large prospective study is now testing whether selegiline with or without vitamin E can slow progression of Parkinson's disease (*JAMA*, 258:881, 1987).

EXPERIMENTAL DRUGS—Pergolide (*Permax*) is a long-acting dopamine agonist that may soon become available in the USA. Like bromocriptine, it is more effective when given with *Sinemet* (JE Ahlskog and MM Muentner, *Mayo Clinic Proc*, 63:969, Oct 1988; SA Factor et al, *J Neurol Neurosurg Psychiatry*, 51:529, 1988). Few studies comparing pergolide and bromocriptine are available; the two drugs have similar adverse effects.

Lisuride is a dopamine agonist not available in the USA that, unlike bromocriptine or pergolide, is water soluble and can be infused subcutaneously through a pump. Such infusions result in constant drug levels that can be useful in some patients with response fluctuations (JA Obeso et al, *Ann Neurol*, 19:31, 1986).

Sinemet CR, a controlled-release formulation combining levodopa 200 mg and carbidopa 50 mg will probably soon be available in the USA (JM Cedarbaum et al, *Clin Neuropharmacol*, 11:168, 1988; JT Hutton et al, *Arch Neurol*, 45:861, Aug 1988). *Sinemet CR* decreases but does not eliminate response fluctuations.

ADJUNCTIVE DRUGS—Depression commonly accompanies Parkinson's disease and must be treated, if present, for the patient to benefit adequately from antiparkinson drugs. Tricyclic antidepressants, trazodone (*Desyrel*) or fluoxetine (*Prozac*) may be useful, but MAO inhibitors used for depression cause marked swings in blood pressure in patients taking levodopa; selegiline, the MAO-type B inhibitor used for treatment of Parkinson's disease does not have this effect on blood pressure, but in antiparkinson doses also does not have an antidepressant effect. Propranolol and other beta-adrenergic blockers can be useful if action tremor accompanies the resting tremor of Parkinson's disease (WC Koller and G Herbster, *Arch Neurol*, 44:921, 1987).

CONCLUSION—Levodopa combined with carbidopa is still the treatment of choice for Parkinson's disease. The effectiveness of this combination diminishes with time, however, and the addition of bromocriptine or another dopamine agonist can decrease response fluctuations and enhance the therapeutic effect. Selegiline (deprenyl), an experimental MAO-type B inhibitor given with levodopa, may also prove helpful.

View from the Hill

JAMES E. BRYAN

FEW of us today realize that only a quarter of a century ago, the family physician seemed about to fade out of the American medical scene. The earlier quarters of the 20th century had seen a burgeoning of scientific medicine, a proliferation of specialties and rapid refinement of medical technologies. These developments were accompanied by a notable decline of the family physician's function. In the mid-1960s, a growing popular disenchantment with the profession's response to the people's need for continuing medical care was reflected by articles then appearing in such publications as *Time*, *Life*, the *Saturday Review*, *The Wall Street Journal*, *Science*, *The New York Times Magazine*, the *New Republic* and *Harpers Monthly*. The articles noted, with varying degrees of regret, resignation or approval, the approaching demise of the general practitioner.

Between April 1965 and February 1967, the Family Health Foundation of America (FHFA)—a study and development arm of AAFP's antecedent organization, the American Academy of General Practice—sponsored with the Association of American Medical Colleges a series of conferences devoted to family practice. The conferences focused on defining family practice, developing its core curriculum and formulating plans to stimulate the establishment of family practice departments, residencies and, ultimately, a certification procedure in the specialty of family practice.

Simultaneously, three other major studies were under way: one by a national commission chaired by the late Marion Folsom, former Secretary of the then department of Health Education and Welfare; another by a citizens' commission led by the late Dr. John Millis, president of Western Reserve, and the third by the American Medical Association's Council on Medical Education. The reports of these three bodies converged upon the theme that individuals should have personal physicians who are the central point for integration and continuity of all medical and medically related services to their patients; recognition and status equivalent to other med-

ical specialties should be given to family practice, and there should be a specialty board, certification examinations and diplomate status for physicians highly qualified in comprehensive care.

All these studies, and the conferences sponsored concurrently by the FHFA, were based on the recognition that in the pride of its scientific accomplishments, American medicine seemed to have lost sight of its essential objective: to provide continuing comprehensive care to the whole patient. Indeed, the Millis commission pointed out that precisely because "the science and art of medicine devoted to understanding and treating individual organs and systems have outrun the science and art of understanding and treating the whole man, specialty practice has become more necessary and more attractive." But Sir Theodore Fox, writing in *The Medical Post* in 1965, suggested that the very growth of scientific medicine makes it all the more imperative that the investigator and specialist "be balanced by someone who is concerned with people rather than things."

In a specially commissioned report on the situation confronting family practice in the mid-1960s, I wrote: "What confronts us in medicine today is a societal monstrosity, a profession standing on its head. Its management function—its coordinator—lies at the bottom of the heap and is rapidly being ground out of existence by the pure weight and commotion of the proliferating mass of uncoordinated specialists milling about above it."

The pyramid still stands precariously on its apex. But the specialty of family practice is gaining daily in numbers, in prestige, in popular acceptance and appreciation. Many other primary care physicians, especially general internists, are practicing what is essentially family medicine.

Bringing these revelations to present-day significance, the resource-based relative-value scale (RBRVS) study, produced under congressional mandate by William C. Hsiao, Ph.D., and colleagues at the Harvard School of Public Health, recently became the hottest topic in medical economics, stimulating a profession-wide debate.

In the midst of this debate, *American Medical News* reports that "the positions of the contending medical

JAMES E. BRYAN, Washington Correspondent, *American Family Physician*.

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groups largely coincide with [their] financial interests." The same source reports that each of the score or more specialist groups has retained a consultant to help it present its case.

The RBRVS formula will inevitably be revised, and special concerns, where reasonable and clear, will be accommodated. But some of the reported reactions raise the specter of a confusion of counsel or Babel of tongues such as might lead highly stressed politicians to look for a more simplistic plan for Medicare reimbursements.

The RBRVS proposal essentially offers these advantages or attractions to a free American medical profes-

sion: (1) It would seek to relate compensation to relevant factors in the costs of providing medical services. (2) It would appropriately adjust compensation for the elemental professional skills of patient care. (3) It would greatly strengthen the profession's hand in resisting growing public pressures for federalized medicine. (4) It would render the economic practices of the profession more reasonable and logical to the people.

Indeed, medical fees levied according to a professionally accepted scale of relative values might compensate family physicians in a manner more pleasing to the public, given the high regard of family physicians today.

ATTENTION: CONNECTICUT PHYSICIANS

The Officers and Directors of the Auxiliary to CSMS Cordially invite your spouse to support organized medicine by participating in the varied activities of the Auxiliary.

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The President's Page

Anabolic Steroids and Athletes



As I read the recent stories of violence among athletes at universities around the country, I couldn't help but make a connection with the use of anabolic steroids. The reports of assaults and rapes are a significant threat to the usual safety of college campuses, and add to the overall concerns about the effects of anabolic steroids on athletes other than the deleterious changes in the individual.

These revelations have coincided with the raising of several bills in the Connecticut General Assembly to deal with this problem. The original Public Health Committee Bill #5302 would levy a \$5,000 fine and up to five years in prison for physicians prescribing anabolic steroids for athletic improvement. But it does nothing to stop the more than 90% of these illicit drugs which come from

nonprescription sources. The intent of significantly reducing anabolic steroids in athletes is therefore not accomplished by this legislation. It also potentially puts a physician at risk for legitimate treatment of an athlete, and sets as well a dangerous precedent by controlling a specific drug by legislative mandate.

I believe my testimony on behalf of the State Society was beneficial in clarifying where the bulk of anabolic steroids comes from, explaining that through our CSMS Sports Medicine Committee we have worked diligently to educate those involved about the dangers of their use, and recommending more meaningful legislation, such as making anabolic steroids controlled substances like narcotics. Such a step would control both the rare prescription and give the authorities a means of stopping and penalizing those involved in illegitimate distribution of anabolic steroids.

I believe there must be laws to control this illicit distribution, because our society prizes athletics and winning at all costs so greatly that the individuals involved frequently cannot make rational judgments. I'm reminded of a survey of Olympic hopefuls taken before the last Olympics which showed that a significant number of them would take anabolic steroids if it insured a gold medal, even though it meant dying from the side effects within seven years. Sometimes we have to be protected from ourselves even in a democracy. Witness the carnage from waffling over a motorcycle helmet law.

Let us hope that Connecticut's legislators during this season will come up with a meaningful bill to control anabolic steroids.

Norman A. Zlotsky, M.D.
President



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Reflections on Medicine

Successful Surgery

ROBERT U. MASSEY, M.D.

When I was growing up in the twenties and early thirties there were two surgical operations that we heard most about: tonsillectomy and appendectomy. Almost all of us had had the first, and the second was imminent; someone was always being taken off to the hospital to have his appendix taken out, and the rest of us were simply waiting in line for the inevitable. Doctors, as far as I could tell, made house calls when you had a fever and sore throat, sometimes opened your ear, but their real work was taking out tonsils and appendices. Every now and then you saw a kid with scars and hollow places behind his ears; he had had a mastoid, probably because his mother had not taken him to have his ear drums punctured when she should have.

On the school playground we would stand close around the boy who had just gotten back from two weeks in the hospital; he would pull up his shirt, jerk his trousers down on the right, and show us his angry red scar with the stitch marks on each side; we didn't say much but our imaginations ran wild as we thought of that once gaping wound with doctors and nurses peering into his insides and him being sound asleep all the while. We dimly understood from having heard stories that if they hadn't taken it out when they did his appendix would have burst, and that would have been that for him. Peritonitis had worked its way into the common language, and like rabies and blood poisoning, it was known to be fatal.

Most of the lives that doctors saved, we thought, were saved in the operating room. We knew nothing of social medicine and had no idea that vaccination, pure water, and good food were saving more lives than appendectomies; those things we took for granted. As Dale Smith wrote recently, "Because surgery had relatively little impact on the major causes of mortality in western populations it is often overlooked by social historians attempting to explain the triumphant transformation of medicine in the 19th century. However, successful surgery had profound social effects, as it provided dramatic interventions that relieved pain and prolonged life in numerous cases."¹

Appendicitis, or as it was known before Reginald

Heber Fitz's landmark paper in 1886, typhlitis, was often a fatal disease, "... one of the most serious and fatal of the abdominal affections of young persons," Osler wrote in his textbook in 1892, concluding that "The profession has yet to learn the lesson that perforative appendicitis is in more than three fourths of all cases a surgical affection, . . ." As late as 1939 there were still over 14 thousand deaths annually in the United States from this disease in a population roughly half the size of today's. But by 1986 there were 512 deaths annually from appendicitis, with more than half over the age of 70.² We seem almost to have learned the lesson emphatically quoted in the *Principles and Practice of Medicine* that I used in medical school: "There would be no percentage of deaths from appendicitis, if every case commencing with acute pain and developing tenderness and rigidity of the abdomen and quickening of the pulse were operated upon within 12 hours."

As surgical clerks we read and reread our little volume of Sir Zachary Cope's *The Early Diagnosis of the Acute Abdomen* with its chapter on appendicitis beginning, "It is essential that the earliest signs and symptoms of appendicitis should be appreciated clearly; . . ." To miss *that* diagnosis seemed to us the most mortal of sins, and we rehearsed over and over the classical history, the progression of symptoms, and the signs that we must elicit. We tried to imagine the march of the underlying, invisible pathological changes and correlate them with the visible clinical picture. For most of us this was the first operation we would see, and the first in which we might be allowed to close the skin.

The first operation for diagnosed appendicitis after Fitz's paper was on 20 April 1887.¹ For several reasons the number of lives saved by appendectomy during these past 102 years cannot be calculated. Those who may have died as the result of operation in the absence of disease, or the operated cases that would have recovered anyway cannot be known. There is little doubt, however, that in deaths per thousand, appendicitis was taking more young lives a hundred years ago than AIDS is today.

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2. Vital Statistics of the US 1986, II, 186-7.

ROBERT U. MASSEY, M.D., Professor, Division of Humanistic Studies in Medicine, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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Refusing Life-Sustaining Technology: The *McConnell* Case

JOSEPH M. HEALEY, J.D.

PROPOSERS of patient self-determination greeted the Connecticut Supreme Court's decision in the *McConnell* Case¹ with a combination of relief and surprise. The relief arose from the Court's unanimous decision to allow the family of a patient in "terminal coma" to implement the patient's clearly expressed wish for the removal of a gastrostomy tube providing artificial nutrition and hydration to the patient. The surprise arose from the manner in which the Court arrived at its conclusion, finding an interpretation of the relevant Connecticut statutes² which permitted the removal of the feeding tube. This month's column will review the reasoning of the majority opinion written by Chief Justice Ellen Peters. Next month's column will continue the discussion by examining the implications of the decision.

At the center of the Chief Justice's opinion is the interpretation of The Removal of Life Support Systems Act² "...in which the legislature, cognizant of a common law right of self-determination and of a constitutional right to privacy, sought to provide a statutory mechanism to implement these important rights."³(pp. 698-9) It is important to emphasize that the Act was viewed not as creating or as limiting rights *per se*, but as providing the mechanism for their implementation. The Court found three guiding principles had been identified by the legislature.

First, if a patient, in the eyes of his or her attending physician, is not in a terminal condition, "beneficial medical treatment and nutrition and hydration must be provided." General Statutes § 19a-571. Second, if a patient, to the contrary, is deemed by his or her physician to be in a terminal condition, life sustaining technology may be removed, in the exercise of the physician's best medical judgement, when that judgement has received the informed consent of the patient's next of kin or guardian and when it coincides with the expressed wishes of the patient. General Statutes § 19a-571. Third, even the removal of life sustaining

technology must be done in a manner consistent with providing "comfort care and pain alleviation" for the patient. General Statutes § 19a-573.³ (p704)

Though the Court concluded that these principles clearly permitted the removal of a respirator from a terminally ill patient, it also concluded that it was not equally clear how the possible removal of a gastrostomy tube should be treated. The Court proceeded to address this issue in the context of the Act as a whole. Noting that the Act distinguished between "beneficial medical treatment" (including artificial technology) on the one hand and "nutrition and hydration" on the other, the Chief Justice went on to recognize "a further distinction between artificial technology to assist nutrition and hydration *a fortiori* included within the definition of a 'life support system' and normal procedures to assist in feeding."³ (p704) Making such a distinction would permit the removal from a terminally ill patient of artificial technology in the form of a device such as gastrostomy tube, but would not permit the removal of "normal nutritional aids" such as a spoon or a straw. Such a construction of the Act would permit the withdrawal of the gastrostomy tube in this case without the necessity of addressing the constitutional claims of the parties and would represent an approach consistent with principles of judicial restraint.

Justice Arthur Healey wrote a concurring opinion in which he expressed his agreement with the Court's conclusion but disagreed with using the Court's construction of the statute as the basis. He would have based his conclusion on the common law right to refuse treatment and on the absence of any compelling state interest to outweigh it.

Discussion of the *McConnell* case will continue in next month's column.

REFERENCES

1. *McConnell vs. Beverly Enterprises-Connecticut, Inc.* 209 Conn. 692 (1989).
2. Connecticut General Statutes Sec. 19a-570 - 19a-575.
3. 209 Conn. 692.

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Paul Duray, M.D.
Chairman of Pathology,
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Dorothy Pietrucha, M.D.
Director of Pediatric Neurology,
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Neptune, New Jersey

Allen Steere, M.D.
Chief of Rheumatology/Immunology
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Lawrence Zemel, M.D.
Director of Pediatric Rheumatology,
Newington Children's Hospital
Newington, Connecticut

Moderators

Prabhash Ganguli, M.D.
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BOOK REVIEW

Physician's Odyssey

By Rita Iovino, MD. 36 pp., Randolph Center, Vt., Greenhills Books, 1988.

Poetry is often as obscure and difficult as medicine in its own way. Why in the world would busy doctors spend time reading this short book of poems by a talented pediatrician from Danbury, Connecticut? In short, for pleasure, and because every lesson in humanity offers depth of understanding; the reader can translate both, by hard emotional work, into more sensitive care of human beings. Many of the poems have nonmedical subjects, yet this book teaches a piece of medicine not found in Harrison's or Nelson's textbooks. "The trade," about a Mexican boy with retinoblastoma, will reverberate particularly for physician-readers, who will recognize the emotional tone of the sickroom as well as the medical issues. Not that this is an in-crowd book for doctors. The poems avoid jargon, both medical and poetic. The book welcomes the nontechnical reader who hasn't read 10 poems in a decade, and helps each reader experience strong feelings in sudden recognition. For this reviewer, the recurrent brilliant yellow-orange sunsets and sunrises vividly recalled the quiet exaltation and weary comfort of seeing explosive sunrises at the end of nights on-call. The descriptions of emotional turmoil bring abrupt, acute discomfort, as one inevitably shares sensations that are universal although the details of their precipitants vary.

The Odyssey in the title appears to be autobiographical, and involves living through personal illness; painful life-experience and loss, including identification with patients; depression, and searing insight that proves valuable; and then emerging to a world that keeps its mystery and beauty. The poet remains passionately concerned about many faces of this world, homeless people and the destruction of a pine tree, among others. Rita Iovino's intensity, as in "sunset," is as great and as commanding of attention as a child's.

"Death of a baby" transmits the helpless gropings for meaning and respite that attend this most terrible event. In the process it alludes just enough to myth, subtly echoing the poem's plaintive, heartbreaking counterparts from the Greek Anthology. Readers unfamiliar with such precursors will not, however, miss the tone; these poems are not inbred or enigmatic. Almost all are clear and accessible, so that one need not scratch one's head or feel intimidated. The syntax is not tortured, and so neither is the reader; and the sound and sense exceed the sum of the parts. In other words, these are fine poems.

One can always criticize. Alliteration and internal rhyme occasionally produce distracting comic overtones. Some page-pairings work better than others. An Old

World thrush, the nightingale, obtrudes in a poem that otherwise feels entirely and beautifully American. These flaws are minor: even Babe Ruth struck out sometimes, and every poet who has not calcified continues to develop. One looks forward to seeing future work. Meantime, the strong content of these poems will provoke, disquiet, delight, and enrich, which is to say shake us out of our sleep and make us more sensate, and that is what poetry is for, and why doctors of all people need it.

Henry Schneiderman, M.D.

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AROUND THE STATE

The Philip K. Bondy Symposium "Recent Advances in Endocrinology and Metabolism" will be held in the Mary S. Harkness Auditorium on Friday, 5 May 1989. This program is sponsored by the Yale School of Medicine, Department of Internal Medicine and the *Yale Journal of Biology and Medicine*. For information call the 8Office of Postgraduate and Continuing Medical Education, (203) 785-4578.

"Perinatal AIDS: Impact on Fetus and Mother" is scheduled to be held at the Park Plaza in New Haven, 15 June 1989. It is sponsored by the Perinatal AIDS Study Unit, Division of Maternal-Fetal Medicine, Department of Obstetrics & Gynecology, Yale University School of Medicine, in conjunction with Connecticut Chapter of the March of Dimes and Yale-New Haven Hospital Auxiliary.

Andrew J. Canzonetti, M.D., chairman of the University of Connecticut Board of Trustees, has been selected to receive the 1989 **Robert U. Massey** Award from the Capital Area Health Consortium in recognition of his "outstanding contributions to the advancement of cooperative arrangements among health care providers in the capital region." Dr. Canzonetti, who is senior vice president for health affairs at New Britain General Hospital, has been on the University's Board of Trustees since 1976 and chairman since 1980. From 1976 to 1978, he headed its health affairs committee.

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COUNCIL MEETING

Wednesday, March 29, 1989

Attendance

Present in addition to the Vice-Chairman Dr. Joseph S. Sadowski were Drs. Ahamed, Beck, Blum, Bobruff, Bonner, Catrini, Fox, Freedman, Ill, Kamens, McDonnell, Orphanos, Petrie, Robbins, Sosa, Wetstone and Zlotsky.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Sullivan, Mr. Staples, Mr. Tomat (FCMA), Ms. DeLauro (HCMA), Mr. Freberg (NHCMA), and Mrs. Reed (President, Auxiliary).

Absent were: Drs. Chmielewski, Czarsty, Dardick, Eslami, Hollister, Jr., Kaufmann, Lesnik, O'Brien, Reyelt, Jr., Rose, Rubin, Schwartz, Upham, Van Syckle, Villa, Welch, Zanker and Zeppieri.

Resident Physician Section

Rocky Yapp, M.D., chairman of the CSMS Resident Physician Section, addressed the Council and expressed his appreciation for the support and encouragement received from the Council and staff of CSMS. Copies of the March 27, 1989 meeting of the RPS were distributed and Dr. Yapp addressed a resolution that was proposed at the meeting which reads:

"RESOLVED, that the AMA investigate and, if indicated, generate guidelines or proposals for the appropriate compensation of house officers who seroconvert for HIV during, or as a result of work-related incident occurring during their training as house officers."

Following discussion, it was VOTED to approve the resolution and to send it to the delegates to the Council of New England State Medical Societies.

Report of the President

(a) *Legislative Update*—Dr. Zlotsky reported on the current status of the following bills: Physical Therapist Direct Access, Nurse Prescriptive Authority, Anabolic Steroids Usage, Restriction on Fee for Non-Economic Damages, Podiatry, and Medicare Assignment. Dr. Zlotsky testified at many of the committee hearings expressing the Society's position on these bills and the final disposition of the bills will be reported in a CSMS newsletter.

(b) *Governor's Fitness Day at the Capitol*—CSMS co-sponsored this event which was very successful, and over 300 persons were tested for cholesterol, blood pressure and pulse rates. Members of the CSMS Committee on Medical Aspects of Sports did the testing and the CSMS lobbyist and staff were on hand to greet the legislators.

(c) *Pension Administrative Agency*—A copy of the minutes of the meeting of March 22 and the proposed

changes that have to be made in accordance with the 1986 Tax Reform Act were distributed to all members of the Council. Dr. Zlotsky reported that the PAA reviewed a checklist of the reporting and disclosure requirements which had been prepared in accordance with guidelines that had been provided by Wiggin and Dana and that following detailed review, it was ascertained that all reports had been properly filed and all changes that have to be made to comply with the 1986 Tax Reform Act do not have to be completed until March 31, 1990. It was voted to approve the minutes as information.

The PAA reviewed and approved the changes presented by Mr. Richard Brandt, pension actuary, some were mandated and others were recommended changes. Dr. Zlotsky reviewed each of the changes in detail and following discussion, it was VOTED to approve the recommendations of the PAA as presented.

(d) *Charitable Trust*—In accordance with previous Council Action, Dr. Zlotsky was asked to submit a list of trustees and to submit the names to the Council for approval. It was VOTED to approve the following list submitted by Dr. Zlotsky to serve as Trustees of the Trust:

Fairfield - Bertram Grossman, M.D., Norwalk
Hartford - Leonard Kemler, M.D., Hartford
Litchfield - George Rubin, M.D., Torrington
Middlesex - Vincent J. Catrini, M.D., Middletown
New Haven - David Silverstein, M.D., Derby
New London - Thomas H. Lesnik, M.D., Norwich
Tolland - Virginia Riggs, M.D., Enfield
Windham - Edward Sawicki, M.D., Willimantic

Executive Director - Timothy B. Norbeck,
New Haven

Council Member - Howard Wetstone, M.D.,
Hartford

Council Member - Joseph Czarsty, M.D.,
Oakville

Council Member - Turpin Rose, M.D.,
Danbury

(e) *Connecticut Physicians Guild*—It was VOTED to approve the following individuals as officers of the Connecticut Physicians Guild:

Officers

President-CSMS Executive Director (by title)

Vice President-CSMS Treasurer (by title)

Secretary/Treasurer-CSMS Controller (by title)

(f) Dr. Zlotsky reported, that this being his last Council meeting as president, he wish to state that it has been an honor to serve as the CSMS president and one

which he approached with some trepidation, but it has been a very rewarding experience for him and he hoped also for the Society. He expressed his thanks and appreciation to staff members and the Council for their support and for being given the opportunity to serve as the CSMS president.

Report of the Executive Director

Tim Norbeck reported on the following items:

- (a) *Washington Monument*—A letter has been received from James H. Sammons, M.D., Executive Vice President of the AMA, outlining a fundraising campaign in which they are involved to restore the AMA Commemorative Stone which is housed in the Washington Monument. The stone was originally donated to the Monument in 1855 and has fallen victim both to time and vandalism. The goal is to raise a minimum of \$33,000 which will go toward refurbishing the original stone, which will remain in the Monument, as well as the creation of a duplicate stone which will be placed in the AMA's new headquarters building. Contributions over \$33,000 will be donated to the National Park Service for other restorative work on the Washington Monument. Two-thirds of the needed funds have already been received from individual physician contributors. In order to reach their minimum goal by June 1, all State Medical Societies have been requested to contribute \$.05 per member. Although the CSMS contribution at \$.05 per member would be \$280.65, it was VOTED to contribute \$500.00 to the fund.
- (b) *Mandatory Assignment*—Florida Medical Association is currently in the midst of a controversy over medicare assignment with their state legislature, and Mr. Norbeck was invited to speak to the Florida Leadership conference on the subject and later asked to return to Florida to make presentations to five county medical associations informing them of the Connecticut program. As of the present, Florida will be adopting the Connecticut voluntary Medicare program. The Florida Legislature convenes in April and a mandatory assignment bill will be discussed at that time.
- (c) *Speaker-House of Delegates*—It was reported that Dr. Jerald Schenken of Omaha, Nebraska, and member of the AMA Board of Trustees, had agreed to address the CSMS House of Delegates on May 10.
- (d) *Insurance Commissioner*—A letter has been received from the Connecticut Insurance Commissioner, Peter Kelly, pointing out that physicians throughout the state should be aware that there are two bogus companies soliciting physicians for malpractice insurance coverage, Medical Liability Purchasing Group, Jeffersonville, Indiana and Professional Risk Insurers Management Exclusive Company Limited located in St. Vincent's, West Indies; both companies are not licensed in Connecticut. This information will be published in the CSMS Newsletter.

Update on M.D. Health Plan

Dr. Vincent Catrini reported that the progress being made in M.D. Health Plan is very encouraging and that over 17,000 members have been enrolled which exceeds the original projection for this period. The cash flow is excellent and the entire picture seems very promising. The aims and goals for MDHP are directed to quality and quality assurance.

CHA Health Manpower Information Center Meeting

At the request of the CSMS President, Dr. Jerome Freedman attended the subject meeting and submitted a written report outlining the demographics in the state, which indicate that there will not be enough graduates from high schools in Connecticut in the next 15 years to satisfy the needs of the health professions. It was VOTED to refer the report to the Committee on Allied Health Services and the Joint Practice Committee for study and report. The Joint Practice Committee would address itself to the nursing shortage.

Report on CMMI and CMIC Activities

- (a) In accordance with Council action, prior to each House of Delegates meeting, a report is presented on CMMI and CMIC activities. Dr. James Orphanos reported CMMI is now an advisory body to CMIC and that he has written a letter to the Chairman of CMIC regarding his concerns about the future of CMMI. CMIC is entering its fifth year of operation and is a very successful company and feels it is time for the Board of Directors to discuss the present and future aims of the company. He recommended reading a book entitled "The Silent Banker" written by Mr. Tobias from the insurance industry that deals with mutual insurance companies that are self-perpetuating and in view of the Tax Reform Act of 1986, he has advocated that CMIC become a stock company. The Tax Reform Act of 1986 has cost CMIC over one million dollars in taxes and the Physicians Insurance Association of America (PIAA) is working with the Internal Revenue Service trying to lessen the impact of this legislation. In early 1989, CMIC had a defense counsel meeting in Hartford which was very well received. He reported that a CMMI Board meeting will be held on May 8th.
- (b) CMIC submitted, for Council review, a list of physicians nominated by the counties for election to the Board of Directors of CMIC. It was VOTED to approve these as submitted. Terms are for three years.

Sultan Ahamed, M.D., New London County
Dennis Huskins, M.D., Fairfield County
Stanley Keating, M.D., Hartford County
David McKee, M.D., Fairfield County
Stewart Petrie, M.D., New Haven County
George Rubin, M.D., Litchfield County

Commissioner of Health Services vs. Harold Kadish

Dr. Zlotzky discussed the recent case that appeared in

the Connecticut Law Journal whereby the court judged that the proceedings of peer review committees are discoverable by state administrative agencies, since these are not deemed to be "civil" proceedings which are shielded by state statutes. (38-19a (d). An appeal of this judgment has been filed. CSMS counsel is monitoring developments in this case and will advise appropriate action by CSMS. Following lengthy discussion, it was VOTED that the Council notify all CSMS members that there exists increased risk to them for any peer review activities they may undertake, providing legal counsel agrees that such risk exists.

Mandatory AIDS Screening for Elective Surgical Patients

Following lengthy discussion on the pros and cons for mandatory screening, it was VOTED that the Council recommends that the policy of mandatory AIDS screening on admission to a hospital be adopted and that a resolution to that effect be transmitted to the CSMS House of Delegates for approval. It was further VOTED to instruct the CSMS lobbyists to vigorously oppose SB bill 812 on this subject which was introduced in the legislature.

Nominations

At the last Council Meeting, it was voted to rename the Committee on Allied Medical Services the Joint Practice Committee and to form a new Committee on Allied Health Services that would be chaired by Dr. Zlotzky who was to submit a list of nominees for the committee and to restructure the charges to the committee. It was VOTED to approve the following restructured charges to the committees and also to approve the list of nominees for the Committee on Allied Medical Services:

- (a) *Joint Practice Committee*—The Council shall annually nominate to the House of Delegates a Joint Practice Committee to consist of no less than eight members and shall nominate the physician co-chairman thereof. The function of the committee shall be to arrange and maintain liaison and conference with groups such as the Connecticut Nurses Association, the Connecticut League for Nursing, and other organized nursing groups for the purpose of promoting continued dialogue and study among representatives of such groups concerning the professional, legal, and socioeconomic aspects of their interrelationships, and ways and means of achieving jointly their common objectives.
- (b) *Committee on Allied Health Services*—The Council shall nominate to the House of Delegates a Committee on Allied Health service to consist of no less than

nine members and shall nominate the chairman thereof. The function of the committee shall be to arrange and maintain liaison and conference with appropriate organizations of limited licensed health care providers including but not limited to physical therapists, psychologists, optometrists, podiatrists and chiropractors for the purpose of promoting continued dialogue among representatives of such groups concerning the professional, legal, and socioeconomic aspects of their interrelationships and the ways and means of achieving jointly their common objectives.

- Norman A. Zlotzky, M.D., Rockville, Chairman (Orth)
- Ronald Berger, M.D., Winsted (Oph)
- Elizabeth Rocco, M.D., Middletown (Oph)
- Peter Zeman, M.D., Hartford (Psych)
- Ellen Fischbein, M.D., Cheshire (Psych)
- Charles Marshall, M.D., Norwalk (Phys)
- John O'Brien, M.D., New Haven (Phys)
- Enzo Sella, M.D., Hamden (Orth)
- F. Scott Gray, M.D., Danbury (Orth)
- Sally Rudicell, M.D., New Haven (Orth)
- Vincent Turco, M.D., Hartford (Orth)
- John J. O'Brien, M.D., Hartford (Orth)

These names will appear in the 1989-90 Nominating Schedule.

IPA Nominees

In accordance with the CSMS-IPA Bylaws, the CSMS is requested to nominate four physicians for two year terms, one of which should be a primary physician as defined in the IPA Bylaws. It was VOTED to approve the following nominees:

- Vacancy (GS) (T)
- Beatrice S. Desper, M.D., Bristol, (OBG) (H)
- Shelby J. Galloway, M.D., New Haven, (RAD) (NH)
- Charles A. Shooks, M.D., Willimantic, (IM) (W)

These names will appear in the 1989-90 Nominating Schedule.

Life Members

It was VOTED to receive the following list of Life Members as information:

- Wayne D. Ross, M.D., West Hartford (H)
- Elwood F. Ireland, M.D., Southport (F)
- Samuel J. Cornett, M.D., Cromwell (M)

N.B.: The foregoing is a summary of the proceedings and actions of the Council on March 29, 1989. Detailed minutes of the meeting are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.

Manuscripts

Manuscripts should be submitted to **Robert U. Massey, M.D., Editor, CONNECTICUT MEDICINE**, 160 St. Ronan St., New Haven, CT 06511, in **original and one duplicate copy**. The author should retain another copy for his records. A covering letter should identify the person (with the address and telephone number) responsible for negotiations concerning the manuscript; the letter should make it clear that the final manuscript has been seen and approved by all authors.

Author Responsibility

The author is responsible for all statements made in his work, including changes made by the copy editor. Manuscripts are received with the explicit understanding that they are not simultaneously under consideration by any other publication. All manuscripts are acknowledged upon receipt and are followed up by notification of either acceptance, revision or rejection. Although rejected manuscripts are generally returned to the author, the *Journal* is not responsible for loss. Accepted manuscripts become the permanent property of the *Journal* and may not be published elsewhere without written permission from both the author and the *Journal*.

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Manuscript Preparation

Copy must be typewritten double-spaced on (8½ x 11-inch) heavyduty, white, bond paper. This requirement applies to all text elements: references, legends, footnotes, and others. Pages should be numbered consecutively. Authors should generally follow *JAMA* style or consult *Manual for Authors & Editors*, Seventh Edition, 1981, compiled for the AMA and published by Lange Medical Publications, Los Alto, California.

Titles and Author's Names

The first page of the manuscript should include (A) title of paper; (titles should be short, specific, clear, and amenable to indexing); (B) name of author(s), including first name(s) and with academic degree(s); (C) List hospital positions for each author and any institutional or other credits. If an author's present affiliation is different from the affiliation under which the work was done, both should be given. Include academic appointments when applicable.

Authors should express all measurements in *Système International (SI)* units, but they may include older conventional units in parentheses if they desire.

Abstracts

The second page should contain an abstract of not more than 150 words. This abstract should be factual, not descriptive, and should present the reason for the study, the main findings (give specific data if possible), and the principal conclusion. Do not include a summary.

References

The following minimum data should be typed double-spaced: names of all authors, complete title of the article cited, name of journal abbreviated according to *Index Medicus*, year of publication, volume number, and first and last page numbers. All

references must be cited in the text. They should be arranged according to the order of citation, and not alphabetically. All references must be numbered consecutively. Numbered references to personal communications, unpublished data and "in preparation" are unacceptable. If absolutely essential, such material may be incorporated in the appropriate place in the text or as a footnote. Sample references are as follows:

1. Jones J: Necrotizing *Candida* esophagitis. *JAMA* 1980;244: 2190-2191.
2. Kremer H, Kellner E, Schierl W, et al: Ultrasonic diagnosis in infiltrative gastrointestinal diseases. *Dtsch Med Wochenschr* 1978;103 (June 9): 965-966. Abstracted, *JAMA* 1978;240:2784.
3. Influenza vaccine—recommendations of the Public Health Service Advisory Committee on Immunization Practices. *MMWR* 1979;28:231-238.
4. Fischer DH: *Growing Old in America*. New York, Oxford University Press, 1977, pp 210-216.

Tables

Data presented in tables should be self-explanatory and should supplement, not duplicate, the text or figures. Excessive tabular data are discouraged. Each table should be typed double spaced, including all headings, on separate sheets of 8½ x 11-inch paper. Oversize papers should not be used. Instead, repeat heads and stubs on a second sheet for tables requiring extra width. Number tables consecutively with respect to citation in the text. Each table must have a title.

Illustrations

Figures should be professionally drawn and photographed, if possible. Glossy, clear black and white photographs should be submitted.

Line drawings, graphs and charts should be done in India ink on high-grade white drawing paper. Lines should be examined for evenness, breaks, and proper alignment. Lettering and symbols should be clear and of even density throughout. Symbols, lettering, and numbering should be of such proportioned size that when the figure is reduced to *Journal* column width (8 cm) each item will be distinctly recognizable.

Do not send original artwork or black and white negatives.

Each figure should have a label pasted on its back indicating the figure's number, the names of the authors, and the top of the figure. Do not mount the figure on cardboard. Do not write on the backs of figures, nor expose them to paper clips.

If photographs of patients are used, either the subjects should not be identifiable, or their pictures must be accompanied by written permission to use the figure.

Legends for illustrations should be typewritten (double space) on a separate sheet with numbers corresponding to the figures.

Drug Names

Generic names should be used. If an author so desires, brand names may be inserted (parenthetically.)

Permissions

Materials taken from other sources must be accompanied by a written statement from both author and publisher giving permission to the *Journal* to reproduce such material. If clearances are required by the author's institution, statements concerning such clearance should be provided in the manuscript.

Review and Action

All manuscripts are subject to review by referees in appropriate fields of medicine. Authors are usually notified within three to six weeks as to the acceptability of a manuscript, but sometimes longer delays are unavoidable.

IN MEMORIAM

BRUNN, FREDERICK M., Columbia College, Physicians & Surgeons, 1970. Dr. Brunn was an orthopedic surgeon in the Litchfield County area since 1977. He was a member of the Litchfield County Medical Association and the Connecticut State Medical Society; died 16 March 1989 at the age of 43.

CAREY, THOMAS B., Albany Medical College, 1944. Dr. Carey was a general practitioner in the Hartford County area since 1947. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died 7 January 1989 at the age of 76.

CARROLL, JAMES E., Boston University, 1925. Dr. Carroll was an internist in the Hartford County area since 1925. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died 14 February 1989 at the age of 91.

DURKEE, RALPH, Harvard, 1936. Dr. Durkee was an internist in the Hartford County area since 1938. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died 31 March 1989 at the age of 82.

DYER, CHARLES E., Tufts, 1928. Dr. Dyer was a general practitioner in the New London County area since 1929. He was a member of the New London County Medical Association and the Connecticut State Medical Society; died 14 February 1989 at the age of 85.

EATON, HARRY E., University of Vermont, 1949. Dr. Eaton was a general practitioner in the Windham County area since 1952. He was a member of the Windham County Medical Association, the Connecticut State Medical Society and the American Medical Association; died 27 January 1989 at the age of 67.

ECKELS, HOWARD S., Hahnemann, 1948. Dr. Eckels was an obstetrician and gynecologist in the Fairfield County area since 1954. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died 7 April 1989 at the age of 69.

LAHEY, WILLIAM J., Harvard, 1942. Dr. Lahey was an internist in the Hartford County area since 1946. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died 24 January 1989 at the age of 72.

MANNIX, HENRY, Cornell, 1950. Dr. Mannix was a surgeon in the Hartford County area since 1971. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died 26 March 1989 at the age of 61.

MORGAN, WILLIAM O., Georgetown, 1930. Dr. Morgan was a family practitioner in the Fairfield County area since 1933. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died 30 January 1989 at the age of 82.

PALMIERI, MARIO L., Yale, 1932. Dr. Palmieri was a public health officer in the Middlesex County area since 1937. He was a member of the Middlesex County Medical Association, the Connecticut State Medical Society and the American Medical Association; died 15 January 1989 at the age of 83.

QUINTILIANI, ALBERT, Harvard, 1929. Dr. Quintiliani was an obstetrician and gynecologist in the New London County area since 1931. He was a member of the New London County Medical Association, the Connecticut State Medical Society and the American Medical Association; died 2 March 1989 at the age of 88.

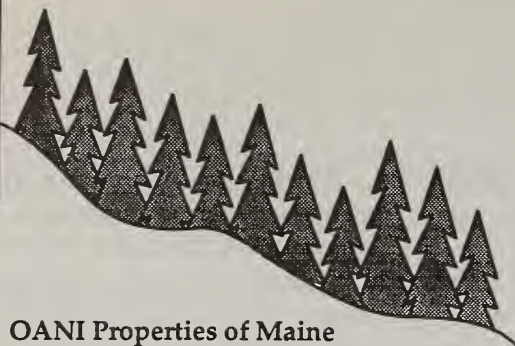
SAIDEL, JOSEPH W., University of Chile, 1938. Dr. Saidel was a general practitioner in the Fairfield County area since 1945. He was a member of the Fairfield County Medical Association and the Connecticut State Medical Society; died 17 January 1989 at the age of 77.

SCHATTEN, SIEGFRIED, New York University, 1931. Dr. Schatten was a general practitioner in the Hartford County area since 1946. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died 16 January 1989 at the age of 83.

SINGER, HOWARD, New York Medical College, 1961. Dr. Singer was an ophthalmologist in the Fairfield County area since 1967. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society and the American Medical Association; died 6 April 1989 at the age of 63.

VINCI, VINCENT J., New York University, 1939. Dr. Vinci was a surgeon in the Middlesex County area since 1939. He was a member of the Middlesex County Medical Association, the Connecticut State Medical Society and the American Medical Association; died 23 February 1989 at the age of 76.

WINTERS, HYMAN W., Johns Hopkins, 1929. Dr. Winters was a general practitioner in the Hartford County area since 1933. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society and the American Medical Association; died 6 March 1989 at the age of 85.



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BRIEF SUMMARY

CONTRAINDICATIONS

There are no known contraindications to the use of sucralfate.

PRECAUTIONS

Duodenal ulcer is a chronic, recurrent disease. While short-term treatment with sucralfate can result in complete healing of the ulcer, a successful course of treatment with sucralfate should not be expected to alter the post-healing frequency or severity of duodenal ulceration.

Drug Interactions: Animal studies have shown that simultaneous administration of CARAFATE (sucralfate) with tetracycline, phenytoin, digoxin, or cimetidine will result in a statistically significant reduction in the bioavailability of these agents. The bioavailability of these agents may be restored simply by separating the administration of these agents from that of CARAFATE by two hours. This interaction appears to be nonsystemic in origin, presumably resulting from these agents being bound by CARAFATE in the gastrointestinal tract. The clinical significance of these animal studies is yet to be defined. However, because of the potential of CARAFATE to alter the absorption of some drugs from the gastrointestinal tract, the separate administration of CARAFATE from that of other agents should be considered when alterations in bioavailability are felt to be critical for concomitantly administered drugs.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Chronic oral toxicity studies of 24 months' duration were conducted in mice and rats at doses up to 1 gm/kg (12 times the human dose). There was no evidence of drug-related tumorigenicity. A reproduction study in rats at doses up to 38 times the human dose did not reveal any indication of fertility impairment. Mutagenicity studies were not conducted.

Pregnancy: Teratogenic effects. Pregnancy Category B. Teratogenicity studies have been performed in mice, rats, and rabbits at doses up to 50 times the human dose and have revealed no evidence of harm to the fetus due to sucralfate. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when sucralfate is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Adverse reactions to sucralfate in clinical trials were minor and only rarely led to discontinuation of the drug. In studies involving over 2,500 patients treated with sucralfate, adverse effects were reported in 121 (4.7%).

Constipation was the most frequent complaint (2.2%). Other adverse effects, reported in no more than one of every 350 patients, were diarrhea, nausea, gastric discomfort, indigestion, dry mouth, rash, pruritus, back pain, dizziness, sleepiness, and vertigo.

OVERDOSAGE

There is no experience in humans with overdosage. Acute oral toxicity studies in animals, however, using doses up to 12 gm/kg body weight, could not find a lethal dose. Risks associated with overdosage should, therefore, be minimal.

DOSAGE AND ADMINISTRATION

The recommended adult oral dosage for duodenal ulcer is 1 gm four times a day on an empty stomach.

Antacids may be prescribed as needed for relief of pain but should not be taken within one-half hour before or after sucralfate.

While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been demonstrated by x-ray or endoscopic examination.

HOW SUPPLIED

CARAFATE (sucralfate) 1-gm tablets are supplied in bottles of 100 (NDC 0088-1712-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1712-49). Light pink scored oblong tablets are embossed with CARAFATE on one side and 1712 bracketed by C's on the other. Issued 1/87

Reference:

1. Eliakim R, Ophir M, Rachmilewitz D: *J Clin Gastroenterol* 1987;9(4):395-399.

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CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

AMBULATORY CARE

Full time or part time position available in June 1989 for physician (preferable background in Family Practice or Internal Medicine) in established Walk-In Center in Branford, CT. Pleasant working conditions; competitive salary; shoreline location. Please send C.V. to: Harry Ardolino, M.D., Coastline Medical Center, 9 Business Park Dr., Branford, CT 06405 or phone (203) 481-0818.

Full or part time position available in Newington Medical Care Center. Excellent salary, benefit, profit sharing and part ownership options available. Please send C.V. to Alex Choi, M.D., Newington Medical Care Center, 955 Main St., Newington, CT 06111.

DERMATOLOGY

Opportunity for dermatologists who seeks satellite office time in area which serves Hartford/Middletown patients. Present dermatologist in this very busy office is relocating. Please respond to: CSMS, c/o DERM/YS.

EMERGENCY MEDICINE

Full time position available in new Immediate Care Facility. Physician will be offered an opportunity for profit sharing in return for day to day management duties. Salary and benefits to be negotiated. Facility is situated in northeast Connecticut. Physician will work with a group of internists. Write, CSMS, c/o EM/QB.

FAMILY PRACTICE

Board Certified/Board Eligible Family Physician wanted for rapidly expanding two man group in central Connecticut. Position available July 1, 1989. Please respond to: Jonathan Rosen, M.D., 1158 Farmington Ave., Bristol, CT 06010. 589-8882.

INTERNAL MEDICINE

Internist to join well-established 11 physician Internal Medicine Group in Central Connecticut, to practice general Internal Medicine. Substantial hospital and office patient population. Liberal salary and benefits. Send CV to: Harold P. Kaplan, M.D., Internal Medicine Associates, P.C., 116 Cook Ave., Meriden, CT 06450.

The Institute of Living (a 400-bed, private, not for profit, psychiatric hospital) is seeking a BC/BE internist subspecialist to join a growing medical program with clinical and teaching responsibilities. Research opportunities available. Contact Charles Boren, M.D., Medical Director, The Institute of Living, 400 Washington St., Hartford, CT 06106.

Internist wanted to join existing division of three faculty geriatricians in academic setting to provide patient care for home care, nursing home, inpatient and outpatient evaluation programs, starting July 1989. Ongoing academic involvement including opportunities for teaching and/or research available, if desired. Competitive salary and benefits, no night or weekend call and four weeks vacation. For information contact: Fitzhugh C. Pannill, III, M.D., Chief, Division of Geriatrics, West Haven VA Medical Center, West Spring St., West Haven, CT 06516.

BC/BE Internist to join three MD Internal Medicine Group in the New Haven area. Send CV to CSMS, c/o IM/NO.

Internist. Board certified. To join three MD Internal Medicine Group in coastal Connecticut. To begin July, 1989. Send CV to: William Colom, M.D., 447 Montauk Ave., New London, CT 06320.

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MISCELLANEOUS

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Oct. '89. Age 30. FLEX. AB elig. MD, University of Iowa, Iowa City, IA; Int., St. Joseph's Hospital, Phoenix, AZ and Children's Hospital, San Francisco, CA; Res., Children's Hospital. Prefers group or associate type practice within commuting distance of the New London/Groton area. Write, Josie Tebben, M.D., 3266 California St., #102, San Francisco, CA 94118.

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Is Adjuvant Systemic Therapy Necessary for All Axillary Node Negative Breast Cancer Patients?

PRADIP M. PATHARE, M.D. AND RICHARD E. PESCHEL, M.D., Ph.D.

ABSTRACT—One hundred eighty-six breast cancer patients with either T1 or T2 primary tumors and negative axillary lymph nodes (N-) underwent only local therapy at Norwalk Hospital from 1978-83. No adjuvant chemotherapy or hormone therapy was given for this favorable group of patients. The actuarial five-year disease free (NED) survival rate for these (N-) patients was 91% ($\pm 3\%$, 95% confidence limits) and the ten-year NED survival rate was 79% ($\pm 8\%$). These NED survival rates are vastly superior to the NED survival rates quoted by the National Cancer Institute (NCI) Clinical Alert for (N-) breast cancer patients who received no adjuvant therapy (67%-77% at three to four years median follow-up time). The NCI Clinical Alert is based on three clinical trials which included (N-) patients with larger tumors than T1 or T2 and excluded patients with small primary tumors. Based on these three clinical trials which demonstrated improved NED survival for (N-) patients treated with adjuvant therapy compared to nontreated patients, the NCI Clinical Alert recommended that adjuvant therapy be considered for all (N-) patients. We conclude that it is premature to recommend that all (N-) breast cancer patients should routinely receive adjuvant therapy until more information is available.

Introduction

ADJUVANT systemic chemotherapy has been shown to increase the disease free (NED) survival and overall survival rates in premenopausal women with localized breast cancer who have histologically positive axillary lymph nodes (N+).¹ Therefore, adjuvant chemotherapy has become standard care for most node-positive premenopausal patients following appropriate local therapy with either mastectomy or excisional biopsy and radiation therapy. Adjuvant tamoxifen has increased the NED survival rate for postmenopausal breast cancer patients who have positive axillary lymph nodes and

hormone receptor positive tumors.¹ Until recently patients with pathologically negative axillary lymph nodes (N-) and relatively small primary tumors were felt to have a relatively good prognosis and adjuvant systemic therapy was not routinely recommended, although certain subgroups of (N-) patients have been identified which may benefit from systemic therapy.¹ In May 1988 the National Cancer Institute (NCI) sent a Clinical Alert to over 13,000 health care professionals throughout the United States.^{2,3} This communication summarized the results of three randomized trials (as yet unpublished by a peer-reviewed journal) on axillary node negative breast cancer patients who had undergone either mastectomy or primary radiation therapy for clinical stage I (T1: primary tumor size of 2 cm or less), clinical stage II (T2: primary tumor size of 2-5 cm), or clinical stage III (T3: primary tumor size greater than 5 cm) breast cancer. Both premenopausal and postmenopausal patients were included as well as patients with tumors that were hormone receptor positive and negative. In the National Surgical Adjuvant Breast and Bowel Project (NSABP) Study B-14, estrogen receptor positive (N-) patients who received adjuvant tamoxifen had a significantly better NED survival rate (82%) compared to a placebo group (77%) with a median follow-up time of four years. In the NSABP Study B-13, estrogen receptor negative patients receiving adjuvant chemotherapy (methotrexate 5-fluorouracil, leucovorin) had an 80% NED survival rate control group who had a 71% NED survival rate at a median follow-up time of four years. Finally, the Intergroup Study INT-0011 of the Eastern Cooperative Oncology Group, the Southwest Oncology Group, and the Cancer and Leukemia Group B randomized both estrogen receptor positive and negative as well as premenopausal and postmenopausal patients to either chemotherapy (CMF+prednisone) or observation. With a median follow-up time of three years the (CMF+prednisone) group has an NED survival rate of 84% versus 67% in the untreated group. The results of each of these three studies were reported to be statistically significant. All three of the studies quoted in the NCI Clinical Alert

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included patients with tumors greater than 5cm (T3) but the exact number was not specified. In addition, the NCI Clinical Alert does not apply to women with very small tumors (<1 cm) because very few of these patients were entered into the INT-0011, NSABP B-13, or NSABP B-14 trials.³ Based on these summarized results, the NCI took the unprecedented step of bypassing the peer review process and recommended that either adjuvant chemotherapy or tamoxifen be considered for all (N-) patients without making available the actual data. While the publication of the details of these studies are eagerly awaited and should contribute to better treatment policies for (N-) patients, the lack of stratification by tumor size (T1, T2, or T3) in the NCI directive has produced confusion and controversy in the medical community and in the minds of breast cancer patients who are seeking optimal treatment. The NCI communication implies that in the absence of systemic adjuvant therapy, the average (N-) patient will have an NED survival of only 67%-77% with a median follow-up of three to four years. Since the three trials quoted in the NCI Clinical Alert excluded many patients with very small tumors, it is doubtful that the NED survival rates of 67%-77% apply to most favorable (N-) patients with T1 or T2 tumors. Therefore, we conducted a review to test the validity of the data summarized in the NCI Clinical Alert for (N-) patients with small breast primaries who received no adjuvant therapy.

Methods

This study is a retrospective review of 186 patients with early adenocarcinoma of the breast who were treated at Norwalk Hospital between 1 January 1978 and 31 December 1983. During the study period, 2,845 cancer patients were treated at Norwalk Hospital and recorded in the tumor registry and 473 patients had a diagnosis of breast cancer. Patients were included in this study if they had small primary tumors (T1 or T2) and clinically or pathologically negative axillary lymph nodes and if they received no adjuvant chemotherapy or hormonal therapy. Patients were excluded if they had histological studies showing other than infiltrating ductal or lobular carcinoma or if they refused proper local therapy (mastectomy or primary radiation therapy). One hundred and eighty six (39%) of the 473 breast cancer patients fulfilled the study requirements. Primary local therapy included a modified radical mastectomy, a total mastectomy with an axillary lymph node dissection, or a partial mastectomy with or without a node dissection and primary radiation therapy. Eighty percent of the patients had pathologically negative axillary nodes and 20% were clinically node negative. We did not separate the pathological node negative patients from the clinical node negative patients; however, we estimate that over 95% of the entire study population were true pathological node negative (N-) patients. The hormone receptor status was not routinely determined during the study period and this patient population includes both estrogen receptor

positive and negative patients. Patient age ranged from 29 to 87 years with a mean age of 60 years. Patients who were 50 years of age or less were considered premenopausal (48 patients) and patients over 50 were considered postmenopausal (138 patients). Primary tumors of 2 cm or less were classified as T1 (131 patients) and larger tumors up to 5 cm were classified as T2 (55 patients).

Actuarial disease free (NED) survival rates with associated 95% confidence limits were calculated using the life-table method.⁴ Patients who died of unknown causes were scored as having died of cancer. The actuarial NED survival rates were compared for premenopausal patients versus postmenopausal patients and for T1 patients versus T2 patients and statistical significance was tested using the standard z-test.⁵

Results

There was no statistical difference in the actuarial NED survival rates for premenopausal versus postmenopausal patients as shown in Figure 1. The five-year NED survival rate for premenopausal patients was 88% ($\pm 10\%$, 95% confidence limits) versus 92% ($\pm 4\%$) for postmenopausal patients. There was no statistical difference in the actuarial NED survival rates for T1 tumors versus T2 tumors as shown in Figure 2. The five-year NED survival rate for patients with T1 tumors was 92% ($\pm 4\%$) versus 90% ($\pm 8\%$) for T2 tumors.

The actuarial NED survival for all 186 patients who received no adjuvant therapy is shown in Figure 3. For the entire patient population, the five-year NED survival rate was 91% ($\pm 3\%$) and the ten-year NED survival rate was 79% ($\pm 8\%$).

Discussion

The recent NCI alert which recommended that adjuvant systemic therapy be considered for all node negative patients prompted us to undertake this study to determine the NED survival for breast cancer patients with T1 and T2 tumors who were node negative and had received no adjuvant therapy.

The five-year NED survival rate for our T1 and T2 patients who received no adjuvant systemic therapy ($91\% \pm 3\%$) is vastly superior to the NED survival rates for the control or untreated patient groups quoted in the NCI clinical alert (67%-77%) with a median follow-up of only three to four years. Indeed, our T1 and T2 patient population who received no adjuvant therapy has a better NED survival rate than any of the treated (chemotherapy or hormone therapy) groups quoted in the NCI alert (80%-84%). Even the ten-year NED survival rate for our patients ($79\% \pm 8\%$) compares favorably to the treated groups in the NCI alert with a median follow up of three to four years. Until the details of the various randomized studies quoted in the NCI alert are published, the discrepancies in the NED survival data in our study versus the NCI alert cannot be completely resolved. However, two factors which explain some of the differences in these survival data are the *inclusion* of T3

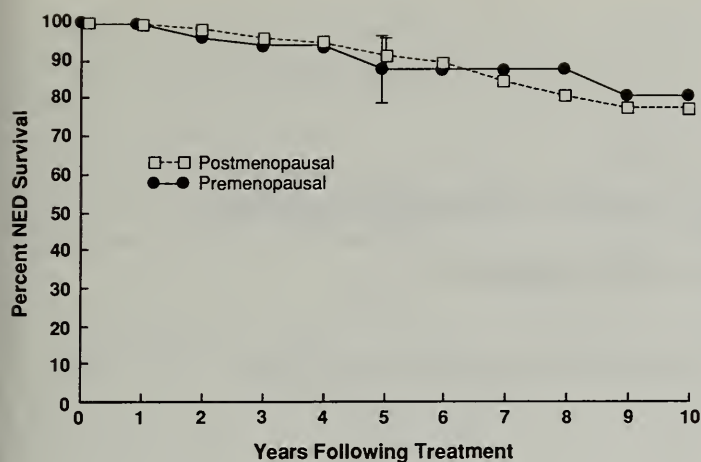


Figure 1

Actuarial disease free (NED) survival for premenopausal versus postmenopausal (N-) breast cancer patients with T1 or T2 primary tumors. Error bars represent 95% confidence limits.

patients and the *exclusion* of patients with very small primary tumors in the studies quoted by the NCI. Therefore, we question the rationale of recommending adjuvant therapy for all node negative patients. Some patients with negative nodes are at increased risk for relapse and may be identified by multiple factors such as large tumor

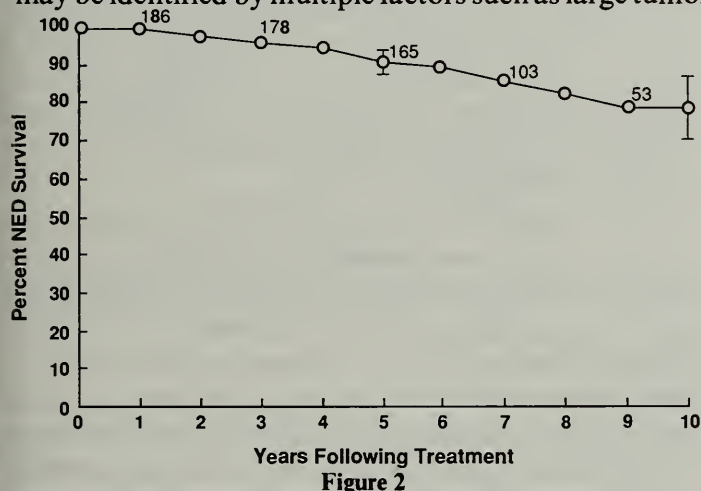


Figure 2

Actuarial disease free (NED) survival for (N-) patients with T1 tumors versus T2 tumors. Error bars represent 95% confidence limits.

size, negative hormone receptor status, degree of differentiation, high thymidine labeling index, etc.¹ These patients should be considered for adjuvant therapy. However, we do not believe there is justification at the present time to recommend that all node negative patients receive systemic therapy. We urge physicians to await the publication of the forthcoming clinical trials before making a final decision about the optimal therapy for all node negative breast cancer patients. We encourage physicians to use the data in Figures 1-3 as a reference when discussing the issue of adjuvant therapy with their patients.

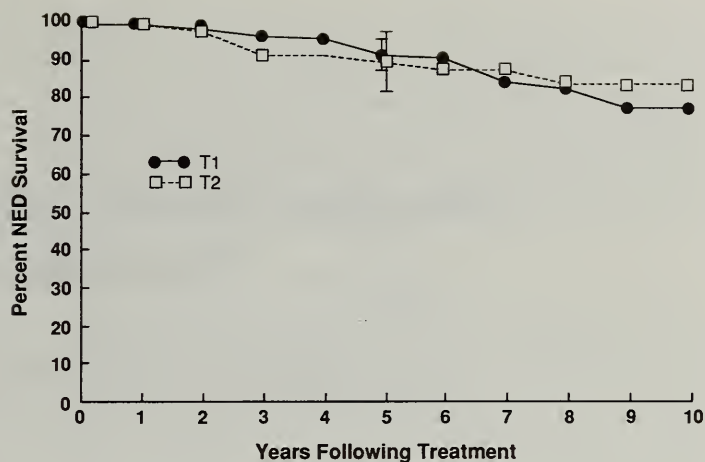


Figure 3

Actuarial disease free (NED) survival for all 186 (N-) patients with either T1 or T2 tumors. Numbers next to the data points indicate the number of patients at risk. Error bars represent 95% confidence limits.

ADDENDUM

Since the submission of our article, the three clinical trials quoted by the National Cancer Institute Clinical Alert have been published by the *New England Journal of Medicine* (1, Fisher B, et al.: A randomized clinical trial evaluating sequential methotrexate and fluorouracil in the treatment of patients with node-negative breast cancer who have estrogen-receptor tumors. *N Engl J Med* 1989;320:473-8. 2, Fisher B, et al.: A randomized trial evaluating tamoxifen in the treatment of patients with node-negative breast cancer who have estrogen-receptor-positive tumors. *N Engl J Med* 1989;320:479-84. 3, Mansour EG, et al.: Efficacy of adjuvant chemotherapy in high-risk node-negative breast cancer. *N Engl J Med* 1989;320:485-90). Our results are significantly better than any of the untreated control groups quoted in these studies. It is likely that these differences are due to a more favorable (N-) patient population treated at Norwalk Hospital (70% T1 tumors and 74% postmenopausal) compared to the patients treated in the three clinical trials published in the *New England Journal of Medicine*. However, after review of these articles, our conclusion remains that it is premature to recommend adjuvant systemic therapy for all (N-) patients.

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Tolerance During Long-Term Administration of Intrathecal Morphine

NABIL M.K. ALI, M.D. AND JAMES S. HOFFMAN, M.D.

ABSTRACT—We studied the time course of development of tolerance in four terminally ill cancer patients who were treated for intractable pain by intrathecal morphine administered by an implanted catheter and pump. The duration of treatment varied from 1.8 to 10.5 months. Our study shows that with disease progression, there was a constant patient-specific time rate of increase in the morphine dose requirements. Hence, for any given patient, the slope of the dose ν time curve is effectively a constant over long periods. We also found that patients tolerate very high doses of intrathecal morphine without serious side effects.

Introduction

Epidural morphine for the relief of intractable pain in the terminally ill cancer patient has been advocated for long-term therapy.¹⁻⁴ Implantable infusion systems for epidural and intrathecal delivery of morphine have been introduced to provide continuous analgesia with minimal inconvenience to the patient.⁵ Because of the limited volume delivered by implantable pumps (1.8-4 ml/day) and the increasingly high drug concentration required for analgesia, subarachnoid delivery is preferable to the epidural route. To our knowledge, there are no reports concerning the temporal development of tolerance to intrathecal morphine administered over long periods, as illustrated in this report. The maximal doses reported range from 4 to 150 mg/day.⁴⁻⁹ We report here the progress of tolerance in four patients with intractable pelvic and leg pain due to malignancy and treated with continuous lumbar intrathecal morphine delivered by an implanted reservoir pump.

Patients and Methods

Four female patients with a mean age of 54, consecutively cared for between February 1985 and March 1986,

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Presented in part at the Fifth Congress of the European Society of Regional Anaesthesia, Malmo, Sweden, 1986.

Reprint requests to: Department of Anesthesiology, University of Connecticut Health Center, Farmington, CT 06032 (Dr. Ali).

were studied retrospectively. They were diagnosed as having untreatable metastatic cancer and suffered from intractable pelvic and leg pain. The varied sites of primary involvement included: cervix (patient 1), vagina (patient 2), ovary (patient 3), and endometrium (patient 4). High doses of oral or parenteral analgesics had previously resulted in excessive sedation without providing adequate pain relief, despite attempts at optimizing therapy. A written informed consent was obtained from each patient to receive an implantable system for continuous intrathecal delivery of morphine. The treatment period extended from the time of implant until they expired, 1.8 to 10.5 months later.

After establishment of general endotracheal anesthesia, the patients were placed in the lateral position. To facilitate needle and catheter placement, flexion of the spine was maintained during the procedure. A longitudinal skin incision, 2-3 cm in length, was made over the third lumbar interspace. A 14 gauge Tuohy epidural needle was introduced through the incision and advanced through the spinal ligaments, while being tested for resistance to air, until the epidural space was identified. The needle was then advanced slowly while applying negative pressure with a syringe until the dura and arachnoid were punctured, and cerebrospinal fluid aspirated. A styletted silicone rubber catheter (I.D.: 0.8 mm; O.D.: 1.5 mm) was advanced through the Tuohy needle 7 cm into the subarachnoid space. Cerebrospinal fluid flow from the outer tip of the catheter confirmed its proper intrathecal placement. A subcutaneous pocket was dissected in the right or left middle quadrant of the abdomen and the Infusaid (R) pump, model 400, was implanted. The catheter was then tunneled subcutaneously across the flank and connected to the pump.

Patients were hospitalized for five to seven days postoperatively during which time the dosage of intrathecal morphine was adjusted to provide optimal analgesia. Hourly respiratory rates were recorded during the first 24 hours. Patients were allowed to ambulate and return to normal activity when possible. Following discharge, the patients returned every two to three weeks for pump

refills and adjustment of morphine dosage. In order to prevent the pump from emptying completely, strict adherence to the refill schedule was maintained. The capacity of the pump is 50 ml and the daily flow rate in the pumps used in our patients varied from 1.8-2.7ml. Preservative free morphine sulfate, prepared by the hospital pharmacy on demand, was used.

Results

Pain relief was initially achieved in all patients during the early postoperative period; all patients required a dose increase on the first postoperative day because of recurrence of pain. Dose requirements in the four patients increased 30, 75, 23, and 10 fold to a maximum of 27, 68, 62, and 20 mg/day over a period of 10.5, 8.9, 4, and 1.8 months respectively (Fig. 1). The concentrations of morphine used ranged from 0.5 to 38 mg/ml.

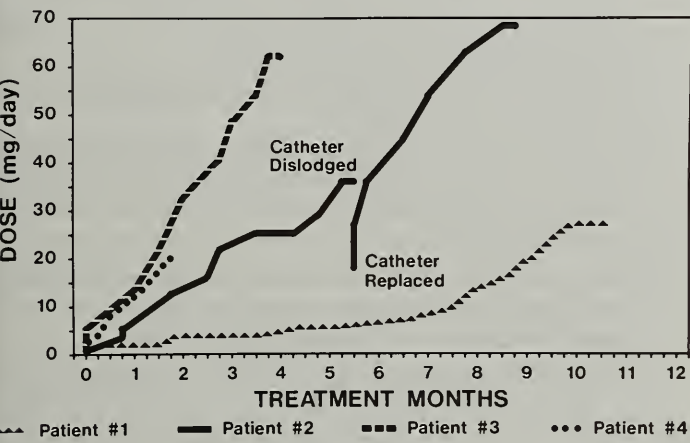


Figure 1

Intrathecal morphine: Dose requirements during long-term administration.

Although the intensity of pain was markedly reduced when compared to the preoperative state, supplemental analgesia in the form of anti-inflammatory drugs and methadone in low doses was occasionally needed in all patients as their disease progressed. The patients who suffered from ovarian and endometrial cancer had more rapid pain progression which required a higher rate of dose increase than the patients suffering from cervical and vaginal cancer.

Side effects, such as clinically apparent respiratory depression, itching, and urinary retention, were not seen in any of the patients, despite high doses of intrathecal morphine. Although moderate nausea and vomiting were reported occasionally by the first patient, the symptoms were not immediately related to any recent dose rate increase. One patient had a spinal headache during the first postoperative day which resolved on the following day after hydration and bed rest. There was no evidence of infection related to the catheter or the pump in any of the patients. The second patient presented with an acute exacerbation of her pain 5.5 months after catheter implantation. Catheter dislodgment was confirmed by the inability to produce a subarachnoid blockade after the injection of lidocaine through the side port of

the pump. The injection of a radio-opaque dye showed that the end of the catheter was lying in a pocket around the pump. A new catheter was implanted and connected to the existing pump, and pain control was reestablished. It should be noted that this patient very rapidly resumed the same constant rate of morphine dose requirement (Fig 1).

Discussion

Information on dose requirements during long-term intrathecal administration of morphine is scarce. In an early report by Coombs,⁵ three patients with intrathecal catheters showed minimal increase in dosage during a relatively short period of time. Two of those patients were treated for four weeks and did not need a significant increase in dosage; the third patient reached a maximum morphine dose of 4 mg/day over a 12-week period. In another early report of one patient,⁶ who was treated with intrathecal morphine for three months, a maximum of 150 mg/day was reached eight days prior to death.

In a later report by Krames,⁷ 11 patients with intrathecal catheters were studied for periods that varied from one to 10 months and variable degrees of tolerance were observed. While one patient required 68.4 mg/day of morphine after four months of treatment, another patient with the same diagnosis needed only 16 mg/day after 10 months of treatment. Coombs⁹ reported a complex case in which pain was extremely difficult to control with high doses of intrathecal morphine (up to 75 mg/day) and trials of intraventricular morphine, intrathecal clonidine, and DADLE (an enkephalin derivative). Pain was eventually, controlled after chemical neurolysis followed by the administration of small increments of intrathecal morphine and bupivacaine.

Tolerance was consistently manifested in our patients who were studied for a total of 25.2 patient months. As the disease progressed, there was a predictable but constant patient-specific rate of increase in the morphine dose requirements (Fig. 1). In other words, for any given patient the slope of the dose v time curve in Fig. 1 is constant. All patients presented with symptoms of nerve entrapment resulting from local invasion in the pelvis by tumor growth. The recurrence of symptoms necessitated frequent adjustment of the intrathecal morphine dose. Supplementation with anti-inflammatory drugs and small doses of methadone was occasionally needed to ensure adequate pain relief. However, when severe pain recurs in spite of increasing the dose, one must rule out technical problems with the implanted system, such as catheter dislodgment, blockage and rupture, or pump malfunction.

The absence of major side effects, despite high doses of intrathecal morphine corresponds to the rapid progression of tolerance in our patients. In a review of six patients with intrathecal catheters and eight patients with epidural catheters, Coombs¹⁰ demonstrated similar findings.

Currently, the highest concentration of preservative-free morphine commercially available is 1 mg/ml. To care for patients with a pump which delivers a fixed flow, frequent concentration adjustments are needed. Therefore, until higher concentrations become available, one must obtain full cooperation of the hospital pharmacy to prepare solutions of the drug. Occasionally, because of the rapid change of symptoms, the drug needs to be prepared on a short notice.

Our observation of higher rates of dose increase in patients suffering from ovarian and endometrial carcinoma is consistent with the faster rate of growths of these tumors.¹¹ In a previous report, we showed that these patients benefit less from this method of pain therapy than patients suffering from cervical or vaginal cancer.⁴

Conclusion

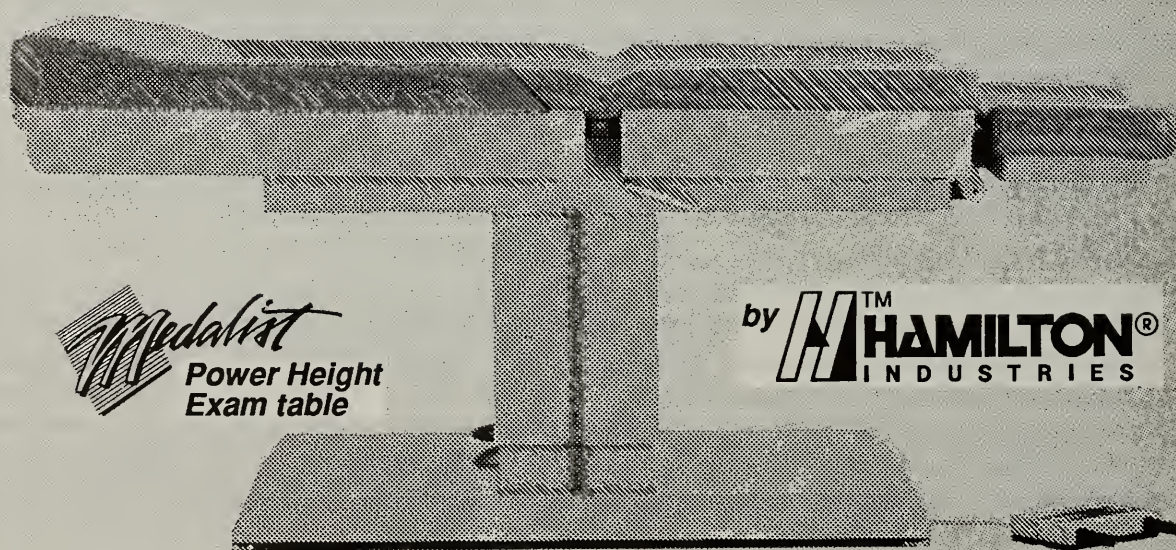
Tolerance appears to be a consistent finding in the long-term intrathecal administration of morphine. It further appears that the time rate of morphine dose increase, as reflected by the straight line slopes of the curves shown in Fig. 1, is a near-constant value that is specific for each patient and the associated disease causing the pain. Frequent dose adjustments and careful follow-up of patients are needed to ensure adequate analgesia. The absence of serious side effects, despite very high doses of intrathecal morphine, is of significance. Technical problems with the implanted system should be ruled out if severe pain recurs in the face of increasing the dose.

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Pain Therapy for Pancreatic Carcinoma with Neurolytic Celiac Plexus Block

RAYMOND SQUIER, M.D., JEFFREY S. MORROW, M.D.,
AND ROBIN ROMAN, M.D.

ABSTRACT—The past year's experience of the Pain and Regional Anesthesia Service at Hartford Hospital with neurolytic celiac plexus blockade for pancreatic cancer has been reviewed. The series includes eight patients with intractable pain from pancreatic cancer as well as two patients with pain from other abdominal malignancies. Nearly all patients noted good to excellent analgesia for up to 11 months. The only complication noted was one episode of mild, transient hypotension. Neurolytic celiac plexus blockade is a safe and effective means to relieve the terminal pain associated with not only pancreatic cancer but also other abdominal malignancies.

PANCREATIC carcinoma has always carried a grim connotation. Survival rates of 10% after one year, and 1% to 2% after five years, justify this notion. It is now fourth among causes of death from cancer in the United States, accounting for over 20,000 deaths annually. To make matters worse, its incidence has risen 300% since 1930 with approximately 25,000 new cases each year. With metastases appearing in over 80% of patients at the time of diagnosis, it is easy to see why the median survival is only six months.¹

Pain is a dominant feature of this disease in over 90% of patients, and this pain is surely enhanced when they realize the prognosis. Patients are left with the intolerable prospect of a short yet painful time to await death. Conventional means to deal with pain using narcotics become unsatisfactory at some point in the progression of the disease so that patients are relegated either to die in great pain or in a narcotic-induced coma. The anesthesiologist has a chance to provide a third option with a neurolytic block of the celiac plexus. Such blocks can either completely relieve pain or provide sufficient analgesia to allow patients to be managed on modest doses of narcotics.

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In patients with carcinoma of the pancreas, severe intractable pain can be treated successfully by chemical neurolysis of the celiac plexus. Reflecting a nation-wide trend in tertiary care medical centers, celiac plexus blockade is increasingly employed by the Pain Therapy Division of the Department of Anesthesiology at Hartford Hospital. This paper summarizes the clinical features of the technique and reviews the recent experience at Hartford Hospital.

The exact cause of pain with pancreatic cancer is in doubt, but the sympathetic nervous system is involved in most cases.² The celiac plexus comprises mainly afferent sympathetic fibers from the abdominal viscera as well as nerve fibers from the greater, lesser, and least splanchnic nerves (T5-T12). Pain pathways consist of afferent input from the pancreas to the celiac plexus, then to the T5-T12 dorsal horns via splanchnic nerves, and finally up to the brain.³ Chemically denervating this sympathetic input with alcohol has been shown by numerous authors to relieve upper abdominal pain resulting from pancreatitis, Crohn's disease, and malignancy, especially pancreatic carcinoma. Analgesia from neurolytic blockade is reported to last months to years.^{2,4,5,6,10}

Anatomy

The celiac plexus is an indistinct collection of nerve fibers lying about the ventral surface of the aorta near the origin of the celiac artery. Cadaver studies have shown that the celiac plexus lies 1.5 cm anterior to the ventral surface of the T12, L1 vertebral bodies.⁷ The anatomic boundaries include the diaphragmatic crura and vertebral bodies posteriorly and the pancreas anteriorly. The aorta constitutes a dorsal medial border to the left while the inferior vena cava lies to the right.

Method

The basic principle involves first performing a diagnostic block with local anesthetic. This allows the physician to determine whether analgesia can be conferred and what degree of physiologic changes can be anticipated (particularly orthostatic hypotension). Further-

more, the patient can know what to expect after neurolysis and can therefore make a more informed decision regarding acceptance of a permanent block.²

The preparation includes making certain that the patient understands that this is not a curative procedure but rather a means to reduce or eliminate pain and to minimize the need for narcotics. At the time of a block the patient must be adequately hydrated and be free of any coagulopathy as assessed by routine coagulation studies. Narcotics should be withheld so that the patient can discern quickly whether the block is effective.

We perform our diagnostic blocks without radiographic control unless we are unable to demonstrate analgesia. (To date we have not had to resort to this aid to our diagnostic blocks). We do perform our neurolytic blocks with radiographic guidance. We have used plain films but recently we have used computed tomographic scanning after Moore and others have shown this to be superior in documenting needle placement.^{4,6,8} In this way we can reduce further the already low risk of such untoward effects as hip numbness or paraplegia.

Technique

We follow the technique described by Moore.⁶ The patient lies prone and 6-inch, 20 gauge needles are inserted bilaterally under local anesthesia 7 cm from the midline at the upper level of the L1 vertebra at a 45° angle toward the T12 vertebral body. After verifying needle position about the aorta, 25 cc absolute alcohol mixed with 25 cc of 0.25% bupivacaine are injected. Patients are given sedation prior to the injection, as the alcohol is initially irritating.

After a block the patient is observed in a recovery area for a short period while continuing to receive intravenous fluids. The patient is instructed not to get out of bed quickly and not without assistance. We usually perform these blocks on patients who are hospitalized for intractable pain, but we have carried them out as outpatient procedures in some instances without difficulties, provided the patients maintain hemodynamic stability and have someone to care for them at home. One precaution is that patients who have been on long-term narcotics need to have their narcotics continued and the dosage reduced gradually so as to obviate narcotic withdrawal symptoms.

Results

Our results have been encouraging. During the past year we have performed 10 blocks; seven for pancreatic carcinoma, but also for other malignancies such as colon cancer and lung cancer with pancreatic metastases. Our success rate of 90% compares favorably with other larger series (see Table 1). One patient's block failed to relieve pain and a repeat block was scheduled a week later; it was assumed that the failure was due to inadequate spread of the neurolytic agent about the celiac plexus. The repeat block was performed with computed tomographic guidance since the initial block was done with

plain films only. Analgesia was noted after the second block. The one patient (VSt) in whom the block failed had widespread metastatic disease and died two weeks later. Duration of analgesia lasted from one to 11 months, with four patients experiencing good relief at the time of this report.

Table 1
Success of Celiac Plexus Blockade Reported in Recent Literature

<i>Author</i>	<i>Year</i>	<i>No. of Patients</i>	<i>Success Rate</i>
Brown	1987	136	85%
Owitz	1983	80	85%
Ischia	1983	28	93%
Singler	1982	6	83%
Moore	1981	20	95%
Thompson	1977	100	94%

Discussion

Good to excellent pain relief can be expected in the vast majority of patients for three months to a year. Repeat blocks are arranged for recurrent pain with greater than 80% success rates reported.⁴ It is felt that recurrent pain is due either to increase in tumor size or nerve regeneration, and so repeat blocks are justified.

In addition to pain relief, there are other benefits of celiac plexus blockade. There is less use of narcotics so that patients may spend their remaining days more able to interact with family and friends. The visceral sympathectomy will cause increased bowel motility and counteract the frequent narcotic induced constipation. Finally, patients have noted improved appetite after a block.^{2,5}

There are complications that deserve mentioning. Most frequently encountered is orthostatic hypotension, occurring 10% to 20% of the time; it apparently results from the dilation of splanchnic vessels,² and is usually transient, lasting a few days to a few weeks. It is easily managed with adequate hydration and slow alterations in position; occasionally, however, oral ephedrine has been necessary. The most feared complication is paraplegia caused by alcohol tracking back up to the epidural space or from an inadvertent intrathecal injection. Fortunately, this is uncommon, appearing only as a rare isolated case report.⁹ However, this prospect should be discussed before obtaining informed consent. The other complications listed (Table 2) are also either rare or only

Table 2
Potential Complications of Neurolytic Blockade of the Celiac Plexus

<i>Complications</i>	<i>Reported Incidence</i>
Orthostatic hypotension	10-20% ^{4,5}
Hip parasthesias	
Paraplegias	
Pleural effusion	
Pneumothorax	Incidental Case Reports
Shoulder pain	
Back pain	
Hemorrhage	
Renal Trauma	
Silent abdomen	

theoretical and unreported. This underscores the safety of this procedure, especially when computed tomo-

graphic guidance is used. One “side effect” we have noted is that of pain manifesting itself at a distant site after successfully ablating the abdominal pain. While obvious potential complications such as pneumothorax need to be considered, we feel that the new pain is the expression of a previously lesser pain that has now been unmasked. This pain sometimes becomes severe and requires the physician to seek its etiology and perhaps request the anesthesiologist to consider a block of a different sort. A frequently asked question by our surgical colleagues is that of the potentially “silent abdomen,” ie, have we removed the warning signals of an acute abdomen? While this is a point to consider, no report exists of an abdominal emergency being hidden by a celiac plexus block.⁵

Finally, concerns regarding widespread retroperitoneal necrosis from the alcohol have been laid to rest after autopsy studies have shown no such findings.²

Conclusion

In summary, neurolytic celiac plexus blockade is a highly effective means of treating the pain of terminal malignancy, particularly pancreatic carcinoma. In addition to its high success rate, it is relatively simple to perform and is largely uncomplicated. Given the typical life expectancy and the great degree of pain these patients suffer, neurolytic celiac plexus block is often one of the few “positive” alternatives that can be offered. This method of pain relief should be used more extensively on the increasing numbers of patients with terminal pain, especially as physicians become more familiar with its indications.

Acknowledgements

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Table 3
Patient Profile

Patient	Pain Relief	Follow-Up
WA	Excellent	Expired four months
JK	Good	Expired one month
MN	Excellent	11 months
JP	Good	Expired four months
VSh	Excellent	Eight months
KW	Good	Expired two months
RL	Good	Four months
BV	Excellent	Five months
ES	Excellent	Expired two months
VSt	Poor	Expired ten days

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Important Advances in Clinical Medicine

Allergy and Immunology

The Scientific Board of the California Medical Association presents the following inventory of items of progress in allergy and immunology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers, or scholars to stay abreast of these items of progress in allergy and immunology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Allergy and Immunology of the California Medical Association and the summaries were prepared under its direction.

Platelet-Activating Factor

PLATELET-ACTIVATING Factor (PAF) is a potent phospholipid mediator of hypersensitivity and inflammatory reactions that may be important to the pathogenesis of allergic and inflammatory disorders. It is structurally distinct from leukotrienes and prostaglandins, but the synthesis of these lipid mediators of hypersensitivity may be linked. Platelet-activating factor is synthesized by human cells important to allergic diseases, including mast cells, neutrophils, monocytes, and endothelial cells. Increased quantities of PAF are released into the sputum of patients with asthma and chronic lung disease, nasal secretions and skin after antigen challenge, and blood after cold challenge of patients with cold-induced urticaria. Severe childhood asthma is associated with a deficiency of the specific acetylhydrolases that metabolize PAF.

Platelet-activating factor has the novel capacity to induce biphasic or prolonged hypersensitivity reactions in vivo. Its inhalation by humans induces eosinophil influx and transient bronchospasm, followed by prolonged airway hypersensitivity that may persist for weeks. Airway eosinophilia and hypersensitivity are hallmarks of asthma, further suggesting that PAF contributes to the development of asthma. Intradermal PAF induces an acute wheal and flare reaction that subsides and is followed by an erythematous, indurated papule. Its capacity to induce such complex reactions may result either

from the wide range of PAF target cells, including eosinophils, neutrophils, monocytes, and endothelial cells, or from complex interactions between PAF and inflammatory cytokines including interleukin-1 and tumor necrosis factor.

Potent, specific PAF antagonists are available and have revealed a critical pathophysiologic role for PAF in some animal models of allergic asthma, anaphylaxis, immune complex disease, and septic shock. Platelet-activating factor antagonists have not yet been tested systematically in human diseases, but preliminary reports suggests that they may be important agents in treating asthma and other hypersensitivity disorders.

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House Dust and Mites

THE House Dust Mites *Dermatophagoides farinae*, *Dermatophagoides pteronyssinus*, and *Euroglyphus maynei* of the family Pyroglyphidae are major sources of multiple allergens in homes. Because mite allergens are continuously produced or linger in the home environment as seasonal breeding mite populations die, mite-

induced allergic diseases are more perennial or nonseasonal than other airborne seasonal allergens such as pollen and mold.

Detailed analyses of house dust from homes in the United States, Europe, and England indicate that many species of mites can be found in the dust in homes. These include plant and animal parasites and predaceous, saprophagous, and stored-product, soil, and fungal-feeding mites. Of this large array, in most homes in geographic areas where true pyroglyphid "house dust mites" are prevalent, *D farinae*, *D pteronyssinus*, and *E maynei* make up 90% to 100% of the mites found in dust samples from mattresses, carpeted floors, and fabric-covered overstuffed chairs and coaches. These mites are most prevalent in high-use areas where human skin scales collect and serve as a source of food.

The percentage of homes containing *Dermatophagoides* species and *Euroglyphus* species is determined by the characteristic relative humidity in a geographic area. In humid geographic areas such as Ohio and similar locations, nearly 100% of homes have mites, and mite densities may be as high as 18,000 mites per gram of dust. In drier climates, such as Denver, fewer than 10% of homes have mites and mite levels are generally well below 100 mites per gram of dust.

In temperate regions, mite density has a seasonal cycle, with high mite levels occurring in the summer or early fall during periods of high relative humidity and lowest mite levels recorded during the dry heating season. The seasonal cycle may be less pronounced or nonexistent in warmer, humid climates; in some locations several density peaks may exist. In drier climates, mattresses are the primary mite foci, where perspiration and evaporative water from the human body provide them with a source of water. In more humid climates, carpets and coaches contain the largest populations because of the constant availability of moist ambient air.

The prevalence of the three major species of mites varies both geographically and between homes in the same geographic area. Most homes are inhabited by more than one species. In coinhabited homes, one species is generally the most prevalent, but the dominant species varies between homes and also between geographic areas.

Because of their cosmopolitan occurrence and the varied patient exposure to multiple species, this ecologic information is of clinical importance in evaluating patients and also in selecting or assessing effective immunotherapy.

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Venom Immunotherapy

IN the ten years since the Food and Drug Administration approved immunotherapy with venoms and venom sac extracts as the treatment of choice for stinging insect hypersensitivity, many groups have reported that only 3% to 5% of venom-treated patients have systemic allergic reactions with subsequent stings, compared with 60% of untreated adults. By contrast, children whose reactions, including urticaria and angioedema, have been confined to the skin appear to have only about a 10% risk of a reaction if stung without immunization; most of those children who do have a reaction when stung have reactions no worse than their original one. A summary of indications for venom immunotherapy includes any systemic manifestation of hypersensitivity in an adult, any extracutaneous manifestation of systemic reactivity in a child, and positive skin tests or radioallergosorbent tests to venom(s).

The success of immunotherapy is judged by the failure to react systemically to a challenge sting. Because the risk of failure of therapy is so small, some authorities think that routine monitoring of venom-specific immunoglobulin (Ig)G antibody levels (whose rise is associated with the appearance of immunity to sting reactions) is unnecessary. Nevertheless, the risk of treatment failure when the antivenom IgG level is less than 0.003 grams per liter is 16%, compared with 3% in patients with IgG values greater than 0.003 grams per liter. When necessary, IgG levels can often be increased by increasing the venom dose to 200 µg per injection of each relevant venom or increasing the frequency of injections.

It is still unknown how long venom immunotherapy should be continued. A high antivenom IgG value is not a sufficient cause for discontinuing venom immunotherapy because the IgG level will fall after therapy is stopped. If treatment is stopped after two years or less of therapy, the risk of reactions to stings rises to about 25% to 30%. One research center reported that after five or more years of uninterrupted venom immunotherapy, the risk of a systemic reaction to sting challenge one, two, and three years after stopping therapy is small. This has been true regardless of whether skin tests are positive or negative and regardless of the titers of venom-specific IgE or IgG at that point. Even so, the risk of future resensitization is unknown. Before these findings can be generally accepted as guidelines for terminating therapy,

the long-term sequelae of stopping venom treatment must be understood.

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Autoimmune Demyelinating Disease

MULTIPLE sclerosis is a demyelinating disease of the central nervous system affecting approximately 250,000 Americans. Although the clinical manifestations are protean, classic features include relapsing or chronic unremitting paralysis. The histologic hallmark is focal areas of demyelination (plaques) within the white matter of the brain and spinal cord. Several lines of evidence indicate that multiple sclerosis is an autoimmune disorder. As with many autoimmune diseases, a susceptibility to multiple sclerosis is associated with certain HLA-D genes—immune response genes that encode the class II molecules of the major histocompatibility complex. These molecules are necessary for antigen recognition by CD4+ lymphocytes. Investigators have found an increased number of class II-bearing cells and a predominance of CD4+ T cells in demyelinating multiple sclerosis lesions.

Experimental allergic encephalomyelitis (EAE) is the prototypic model for autoimmune demyelinating disease. It occurs in certain strains of mice and other mammalian species following immunization with the autoantigen myelin basic protein (MBP), the major constituent of central nervous system myelin. Experimental allergic encephalomyelitis can also be induced by adoptive transfer of MBP-specific CD4+ T cells into naive recipient mice. As with multiple sclerosis, susceptibility to EAE is associated with certain class II genes of the major histocompatibility complex, and antibodies to these molecules can prevent EAE. Further, a predominance of class II-bearing cells and CD4+ T cells is found in the demyelinating lesions of EAE. Individual MBP-specific CD4+ T-cell clones that are class II restricted have been isolated that mediate EAE. These T cells are all descendants from a single clone that causes chronic relapsing paralysis and demyelination. The identification of these clones allowed us to characterize the T cells involved in autoimmune demyelination and to further elucidate the role of the major histocompatibility complex. We found that a limited number of MBP-specific CD4+ T cells cause EAE, and it has been reversed with antibodies to the antigen-specific receptors on these T cells. As in patients with EAE, T cells bearing a restricted number of T-cell

receptors have been found in the brain and cerebrospinal fluid of patients with multiple sclerosis.

Contemporary therapies for multiple sclerosis focus on modalities that have been effective in other autoimmune diseases. The use of cyclophosphamide, total lymphoid irradiation, and the use of synthetic copolymers are all promising experimental approaches to the treatment of multiple sclerosis. Therapy with monoclonal antibodies directed against specific T-cell subsets and T-cell receptors holds promise.

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Spacers and Reservoirs in Delivery Systems

SPACERS and reservoirs were developed to aid the delivery of drugs from metered-dose inhalers. These devices, which are attached to the inhalers, should hold the aerosolized spray, making synchronizing between a metered-dose inhaler actuation and inhalation less critical; allow aerosolized droplets to evaporate to a fine mist, delivering the maximal amount of drug to the lungs; and decrease oropharyngeal deposition. β -Adrenergic agonists delivered by metered-dose inhalers in doses of as much as six times those normally recommended, with or without a spacer, give bronchodilation equivalent to nebulizers in patients with acute and chronic asthma, except in some patients with severe asthma.

Delivery to the lung of a whiff by a metered-dose inhaler—at most 15% of each dose—can be improved by holding the inhaler 3 to 4 cm from a wide-open mouth (some authorities prefer the lips to be closed around the mouthpiece), triggering the inhaler during a slow, deep inhalation over five seconds followed by a ten-second breath-hold. Spacers help improve delivery of a drug in a third to half of those patients who cannot correctly use a metered-dose inhaler but add little further therapeutic effect in patients using a proper inhaler technique.

With β -adrenergic agonists, larger spacers with a volume of 750 ml improve bronchodilator response more than smaller spacers. Five spacers are currently available in the United States: Brethancer (Geigy) and Azmacort (Rorer Pharmaceuticals) tube spacers (80 ml and about 100 ml volume) are specifically for terbutaline and triamcinolone metered-dose inhalers; universal add-

on devices available are the AeroChamber (Forest Pharmaceuticals), a rigid tube (145 ml); InspirEase (Key Pharmaceuticals), a collapsible bag; and Inhal-Aid (Key Pharmaceuticals), a rigid reservoir (both 700 ml). Other spacers with a pear or cone shape, with about a 750-ml volume and for which there are favorable studies, are not available at present.

Studies with β -adrenergic agonists using Brethancer, AeroChamber, and InspirEase show considerable variation in the effectiveness of these devices relative to a metered-dose inhaler alone. Children using isoproterenol in a metered-dose inhaler with Inhal-Aid achieve bronchodilation equal to that with the use of isoproterenol by intermittent positive pressure breathing. The Azmacort tube spacer, InspirEase, AeroChamber, and Brethancer decrease oropharyngeal deposition, and the latter two have been shown to decrease oropharyngeal thrush from inhaled steroids. AeroChamber has been shown to decrease the dysphonia from inhaled beclomethasone dipropionate.

Physicians should have patients demonstrate their inhaler technique. If it is inadequate or if oropharyngeal thrush or dysphonia from inhaled steroids is a problem, then a spacer, used properly, may be of benefit.

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Methacholine Inhalation Challenge for
Diagnosis of Asthma

ASTHMA is recognized clinically by reversible airway obstruction and airways hyperreactivity. Since the 1940s, bronchial inhalation challenges with pharmacologic and antigenic substances have been used to detect airway hyperreactivity. Bronchoconstriction in patients with asthma can be induced by methacholine, acetylcholine, histamine, carbachol, pilocarpine, serotonin, propranolol, methoxamine, adenosine, prostaglandin D₂ or F_{2α}, and leukotrienes C₄ and D₄. Of these, methacholine chloride (Provocholine [Hoffmann La Roche]) has recently been approved by the Food and Drug Administration for inhalation to identify the presence of bronchial hyperreactivity. Methylcholine, a β -methyl homologue of acetylcholine, stimulates the muscarine receptors on bronchial smooth muscle, increasing bronchomotor activity. Although airways hyperreactivity is present in

asthma, the diagnosis is generally made from a combination of history, physical examination findings, and the results of spirometry. Methacholine inhalation challenge is indicated only when the usual evaluation is not diagnostic, such as with patients who have vague symptoms or symptoms such as cough, episodic chest tightness, or atypical dyspnea with normal physical findings and spirometric values. Bronchial challenge may also be used to identify workers who are at risk of occupational asthma developing because of preexisting bronchial hyperresponsiveness. As a research tool, bronchial challenges help clarify the mechanisms of asthma and evaluate new drugs.

Standard procedures for inhaling methacholine have been developed. Factors that influence the response to challenge, such as viral or bacterial respiratory tract infections and pollutants, should be avoided. Various drugs influence the outcome of a challenge, including bronchodilators, cromolyn sodium, and antihistamines. To be challenged, a person should have a baseline forced expiratory volume in one second (FEV₁) of at least 70% of the predicted value. Challenge is done by diluting methacholine from a dry powder and having the patient inhale aerosolized methacholine in ascending concentrations ranging from 0.025 mg per ml of methacholine to 25 mg per ml. Two methods of inhalation are used: five breaths are inhaled from a DeVilbiss nebulizer 646 with a Rosenthal-French dosimeter (0.65 delivery time); or 3 ml of methacholine solution are placed in a Wright nebulizer and the aerosol is administered continuously for two minutes. After each serial concentration, FEV₁ values are determined, and the procedure ends when there is a 20% or greater fall in the FEV₁ value compared with baseline. Results are expressed as either the provocative dose of methacholine producing a 20% decrease in FEV₁ (PD₂₀), the cumulative dose in breath units (1 breath unit = 1 inhalation of 1 mg per ml of methacholine) producing a 20% decrease in FEV₁, or the area under a dose-response curve. More than 90% of those with asthma respond to methacholine by 200 breath units. Bronchoconstriction following the inhalation of methacholine may also develop in persons with allergic rhinitis, chronic bronchitis, bronchiectasis, and cystic fibrosis, indicating airways hyperreactivity; the provocative or cumulative dose is often larger, however.

Methacholine challenge can be associated with severe bronchoconstriction and should be administered only if oxygen, resuscitation equipment, and inhaled and parenteral bronchodilators are available. It is not a test for routine office use but a useful tool for the evaluation of a person with unexplained respiratory tract symptoms.

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Management of Chronic Idiopathic Urticaria

URTICARIA (hives) is a pruritic migratory eruption, characterized by edematous, erythematous wheals of various sizes in the superficial dermis. The term "chronic" refers to symptoms of six weeks' duration or more. Angioedema is a similar reaction confined to the deeper dermis and subcutaneous tissue. The causes of urticaria and angioedema include food, drugs, infection, inhalants, bites and stings, contactants, physical agents, neoplasms, connective tissue disease, and psychic factors. Fatalities from laryngeal edema have been limited almost exclusively to patients with hereditary angioedema and edema due to Hymenoptera stings. Allergy immunotherapy can also result in death. The cause of chronic urticaria usually is not known, hence the term chronic idiopathic urticaria.

For this discussion it is assumed that possible causes have been considered and avoidance has been attempted. Such avoidance may include a diet free of salicylates, benzoic acid derivatives, and tartrazine yellow No. 5, although their potential role in the etiology is controversial. Additionally, potentiating factors such as alcoholic drinks, aspirin, exertion, and heat generally should be avoided. Most patients respond to symptomatic therapy, of which antihistamines of the H_1 inhibitor type are the therapeutic mainstays. Hydroxyzine hydrochloride (Atarax, Vistaril), diphenhydramine hydrochloride (Benadryl), and ciproheptadine hydrochloride (Periactin) are the most effective. Of the three, hydroxyzine is the most potent, with recommended doses starting at 10 to 25 mg four times a day with upward titration. With excessive daytime sedation, 25 to 100 mg can be given at bedtime. Terfenadine (Seldane) with doses as high as 60 mg taken four times during the day can be used in combination with the more sedating H_1 antihistamines. Astemizole (Hismanal) just became available in the United States. It has an exceptionally long duration of action. This and another agent under investigation, ketotifen fumarate, might prove to be useful in refractory patients. Combination therapy should be attempted when single agents are insufficient. Cimetidine, an H_2 blocker, in combination with the H_1 antihistamines, can prove more effective than an H_1 antagonist alone in certain patients. Doxepin, an antidepressant with both H_1 - and H_2 -blocking properties, is potent in vitro and in vivo and can be given at doses of 25 to 75 mg at bedtime.

Sympathomimetic agents such as terbutaline sulfate, 2.5 to 5 mg three times a day, can supplement the antihistamines. In this respect it should be recalled that patients with acute, severe urticaria or angioedema often respond to subcutaneously administered epinephrine, 0.3 ml of 1:1,000 solution for adults. If the disease is severe and not responding to other forms of treatment, corticosteroids may prove useful. After an initial oral boost such as 45 to 60 mg daily for three to six days, tapering and alternate-

day doses, such as 15 to 20 mg every other day, sustain the beneficial effect. Continuous steroid therapy is rarely necessary.

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Asthmogenic Drugs

ASTHMA is a multifactorial disease characterized by abnormal bronchial reactivity and may be perceived as wheezing, cough, chest tightness, or shortness of breath. Drugs may affect this hyperreactivity by any of several mechanisms. For example, drugs may alter bronchial reactivity through an immunoglobulin (Ig) E-mediated allergic mechanism or by the direct pharmacologic effect of a drug. We will focus on the second group of adverse reactions because they are repeatedly implicated in provoking occult or quiescent asthma and in increasing the severity of established asthma.

Foremost in this drug class are the β -adrenergic receptor blockers, which produce bronchoconstriction by directly blocking the β -receptor on the bronchial smooth muscle. This group currently has three main subclasses in clinical use: nonselective β -blockers such as propranolol or nadalol; β_1 -selective (cardioselective) β -blockers—metoprolol, atenolol, for example; and β -blockers with intrinsic sympathomimetic activity, that is, partial agonists such as pindolol. All three classes have been shown to produce deleterious effects. Clearly, the first class produces bronchospasm at the lowest levels and should be avoided in patients with asthma wherever possible. The second was introduced partly because of this limit within the first class. The degree of effect on the β_1 -versus β_2 -receptors is relative, however, and a large enough dose of a selective drug will still produce significant β_2 -blockade. The properties of the third group are less clear; reports of a significant effect on pulmonary function conflict with studies that find no adverse effects. With any of the three classes of β -blockers, the need for administering the drug to a patient must be carefully weighed against the clear theoretic and observed untoward effects. An additional caveat is that timolol, a β -blocker used as an eye drop in glaucoma, is capable of inducing an asthmogenic response. Betaxolol hydrochloride

ride (Betoptic), a β -selective eye drop, appears not to have a similar systemic effect and might be a safe substitute.

Aspirin, along with many other nonsteroidal anti-inflammatory drugs, has been shown to produce asthma in selected patients. These agents are presumed to work by inhibiting the synthesis of certain prostaglandins, with subsequent shunting of the parent prostaglandins through alternate pathways. Nonsteroidal anti-inflammatory drugs that are cross-reactive with aspirin include ibuprofen, indomethacin, piroxicam, naproxen, and meclofenamate sodium, along with several others. The asthmogenic effects of aspirin can be seen in between 4% and 10% of asthmatic persons, who should avoid its use, and in a large number of so-called triad patients with asthma, nasal polyposis, and aspirin sensitivity. Rare reports of hydrocortisone succinate producing asthma in aspirin-sensitive patients warrant avoiding its use in these patients. Other steroids seem not to have this effect. There are many previous reports of a cross-reactivity between aspirin and tartrazine dyes, but these have not been rigorously confirmed and may not, in fact, be real.

Angiotensin-converting enzyme inhibitors such as captopril and enalapril maleate have been shown to produce cough as a side effect, which can mimic uncontrolled asthma. The pharmacologic mechanism is uncertain but is thought to be related to bradykinin metabolism and possibly with its role in axonal transmission. These agents are reported to also alter bronchial reactivity, so the cough may indeed be produced by this mechanism. The incidence of cough is low, with estimates

varying from 1% to 14%, and is often reported after prolonged use of the drugs.

Incidents of asthma following many other therapeutic interventions are reported on a scattered basis. Mast cell degranulation by an unclear but non-IgE-mediated mechanism can lead to bronchospasm. Examples of drugs that act in this manner include iodinated dye and opiates—especially codeine and morphine. Inhaling acetylcysteine can cause broncho-spasm, presumably by a primary irritant effect. The same has been reported for sympathomimetic aerosols, especially isoproterenol. Rare reports of bronchospasm from cromolyn sodium can be found, and, again, bronchospasm is probably due to primary irritation. Also, agents that alter lower esophageal sphincter tone and increase gastric acid secretion can lead to reflux, which may produce nocturnal cough easily mistaken for asthma.

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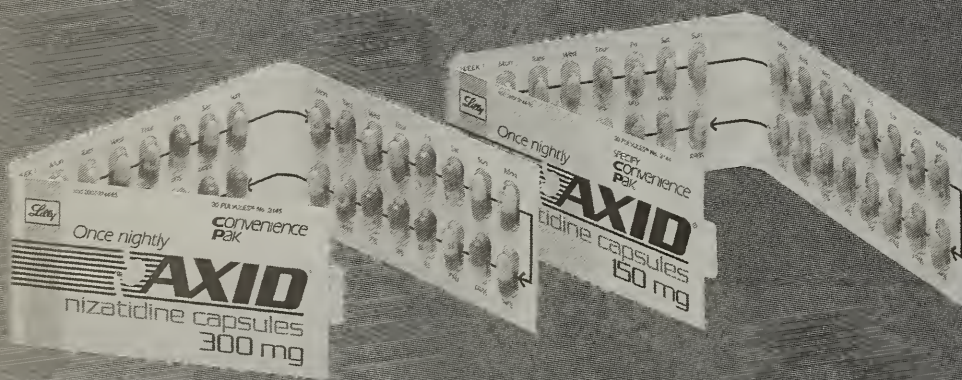
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Indications and Usage: Axid is indicated for up to eight weeks for the treatment of active duodenal ulcer. In most patients, the ulcer heals within four weeks. Axid is indicated for maintenance therapy for duodenal ulcer patients at a reduced dosage of 150 mg b.i.d. after healing of an active duodenal ulcer. The consequences of continuous therapy with Axid for longer than one year are not known.

Contraindication: Axid is contraindicated in patients with known hypersensitivity to the drug and should be used with caution in patients with hypersensitivity to other H_2 -receptor antagonists.

Precautions: General — 1. Symptomatic response to nizatidine therapy does not preclude the presence of gastric malignancy.

2. Because nizatidine is excreted primarily by the kidney, dosage should be reduced in patients with moderate to severe renal insufficiency.

3. Pharmacokinetic studies in patients with hepatorenal syndrome have not been done. Part of the dose of nizatidine is metabolized in the liver. In patients with normal renal function and uncomplicated hepatic dysfunction, the disposition of nizatidine is similar to that in normal subjects.

Laboratory Tests — False-positive tests for urobilinogen with Multistix® may occur during therapy with nizatidine.

Drug Interactions — No interactions have been observed between Axid and theophylline, chlorazepoxide, lorazepam, lidocaine, phenytoin, and warfarin. Axid does not inhibit the cytochrome P-450-linked drug-metabolizing enzyme system; therefore, drug interactions mediated by inhibition of hepatic metabolism are not expected to occur. In patients given very high doses (3,300 mg) of aspirin daily, increases in serum salicylate levels were seen when nizatidine, 150 mg b.i.d., was administered concurrently.

Carcinogenesis, Mutagenesis, Impairment of Fertility — A two-year oral carcinogenicity study in rats with doses as high as 500 mg/kg/day (about 80 times the recommended daily therapeutic dose) showed no evidence of a carcinogenic effect. There was a dose-related increase in the density of enterochromaffin-like (ECL) cells in the gastric oxyntic mucosa. In a two-year study in mice, there was no evidence of a carcinogenic effect in male mice; although hyperplastic nodules of the liver were increased in the high-dose males as compared with placebo. Female mice given the high dose of Axid (2,000 mg/kg/day, about 330 times the human dose) showed marginally statistically significant increases in hepatic carcinoma and hepatic nodular hyperplasia with no numerical increase seen in any of the other dose groups. The rate of hepatic carcinoma in the high-dose animals was within the historical control limits seen for this strain of mice used. The female mice were given a dose larger than the maximum tolerated dose, as indicated by excessive (30%) weight decrement as compared with concurrent controls and evidence of mild liver injury (transaminase elevations). The occurrence of a marginal finding at high dose only in animals given an excessive and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice (given up to 360 mg/kg/day, about 60 times the human dose), and a negative mutagenicity battery are not considered evidence of a carcinogenic potential for Axid.

Axid was not mutagenic in a battery of tests performed to evaluate its potential genetic toxicity, including bacterial mutation tests, unscheduled DNA synthesis, sister chromatid exchange, mouse lymphoma assay, chromosome aberration tests, and a micronucleus test.

In a two-generation, prenatal and postnatal fertility study in rats, doses of nizatidine up to 650 mg/kg/day produced no adverse effects on the reproductive performance of parental animals or their progeny.

Pregnancy — Teratogenic Effects — **Pregnancy Category C** — Oral reproduction studies in rats at doses up to 300 times the human dose and in Dutch Belted rabbits at doses up to 55 times the human dose revealed no evidence of impaired fertility or teratogenic effect; but, at a dose equivalent to 300 times the human dose, treated rabbits had abortions, decreased number of live fetuses, and depressed fetal weights. On intravenous administration to pregnant New Zealand White rabbits, nizatidine at 20 mg/kg produced cardiac enlargement, coarctation of the aortic arch, and cutaneous edema in one fetus and at 50 mg/kg produced ventricular anomaly, distended abdomen, spina bifida, hydrocephaly, and enlarged heart in one fetus. There are, however, no adequate and well-controlled studies in pregnant women. It is also not known whether nizatidine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nizatidine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers — Studies conducted in lactating women have shown that <0.1% of the administered oral dose of nizatidine is secreted in human milk in proportion to plasma concentrations. Caution should be exercised when administering nizatidine to a nursing mother.

Pediatric Use — Safety and effectiveness in children have not been established. **Use in Elderly Patients** — Ulcer healing rates in elderly patients are similar to those in younger age groups. The incidence rates of adverse events and laboratory test abnormalities are also similar to those seen in other age groups. Age alone may not be an important factor in the disposition of nizatidine. Elderly patients may have reduced renal function.

Adverse Reactions: Clinical trials of nizatidine included almost 5,000 patients given nizatidine in studies of varying durations. Domestic placebo-controlled trials included over 1,900 patients given nizatidine and over 1,300 given placebo. Among reported adverse events in the domestic placebo-controlled trials, sweating (1% vs 0.2%), urticaria (0.5% vs < 0.01%), and somnolence (2.4% vs 1.3%) were significantly more common in the nizatidine group. A variety of less common events was also reported; it was not possible to determine whether these were caused by nizatidine.

Hepatic — Hepatocellular injury, evidenced by elevated liver enzyme tests (SGOT [AST], SGPT [ALT], or alkaline phosphatase), occurred in some patients and was possibly or probably related to nizatidine. In some cases, there was marked elevation of SGOT, SGPT enzymes (greater than 500 IU/L) and, in a single instance, SGPT was greater than 2,000 IU/L. The overall rate of occurrences of elevated liver enzymes and elevations to three times the upper limit of normal, however, did not significantly differ from the rate of liver enzyme abnormalities in placebo-treated patients. All abnormalities were reversible after discontinuation of Axid.

Cardiovascular — In clinical pharmacology studies, short episodes of asymptomatic ventricular tachycardia occurred in two individuals administered Axid and in three untreated subjects.

CNS — Rare cases of reversible mental confusion have been reported.

Endocrine — Clinical pharmacology studies and controlled clinical trials showed no evidence of antiandrogenic activity due to Axid. Impotence and decreased libido were reported with equal frequency by patients who received Axid and by those given placebo. Rare reports of gynecostasia occurred.

Hematologic — Fatal thrombocytopenia was reported in a patient who was treated with Axid and another H_2 -receptor antagonist. On previous occasions, this patient had experienced thrombocytopenia while taking other drugs. Rare cases of thrombocytopenic purpura have been reported.

Integumental — Sweating and urticaria were reported significantly more frequently in nizatidine- than in placebo-treated patients. Rash and exfoliative dermatitis were also reported.

Hypersensitivity — As with other H_2 -receptor antagonists, rare cases of anaphylaxis following administration of nizatidine have been reported. Because cross-sensitivity in this class of compounds has been observed, H_2 -receptor antagonists should not be administered to individuals with a history of previous hypersensitivity to these agents. Rare episodes of hypersensitivity reactions (eg, bronchospasm, laryngeal edema, rash, and eosinophilia) have been reported.

Other — Hyperuricemia unassociated with gout or nephrolithiasis was reported. Eosinophilia, fever, and nausea related to nizatidine administration have been reported.

Overdosage: Overdoses of Axid have been reported rarely. The following is provided to serve as a guide should such an overdose be encountered.

Signs and Symptoms — There is little clinical experience with overdosage of Axid in humans. Test animals that received large doses of nizatidine have exhibited cholinergic-type effects, including lacrimation, salivation, emesis, miosis, and diarrhea. Single oral doses of 800 mg/kg in dogs and of 1,200 mg/kg in monkeys were not lethal. Intravenous median lethal doses in the rat and mouse were 301 mg/kg and 232 mg/kg, respectively.

Treatment — To obtain up-to-date information about the treatment of overdose, a good resource is your certified regional Poison Control Center. Telephone numbers of certified poison control centers are listed in the Physicians' Desk Reference (PDR). In managing overdosage, consider the possibility of multiple drug overdoses, interaction among drugs, and unusual drug kinetics in your patient.

If overdosage occurs, use of activated charcoal, emesis, or lavage should be considered along with clinical monitoring and supportive therapy. Renal dialysis for four to six hours increased plasma clearance.

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Additional information available to the profession on request.

Care of Irreversibly Ill Patients: Policy Statement of the Connecticut Chapter of the American College of Physicians

JOSEPH L. BELSKY, M.D., F.A.C.P.

GRADUALLY there is being formulated a broad consensus on approaches to the clinical care of the dying.

There are many physicians and nurses who remember well that a few years ago ill patients died unencumbered by artificial life support while comfort and basic needs were provided. Professionals recognized and accepted the signs of the end of living. Now it is common to approach the end of life in an institution attached to equipment that can slow, but not necessarily prevent, death. In recent years there has occurred increasing examination of this area: What are the ethical medical decisions permitted when dealing with irreversible illness?

A number of opinions, briefs, judgments, and formulations are available, but most of these are the results of legal procedures. There are increasing, but still few, general guidelines.^{1,2}

After joining the Connecticut Civil Liberties Union Foundation in an *amici curiae* brief,³ the Connecticut Chapter of the American College of Physicians approved a statement of policy on the care of irreversibly ill patients. The brief and the policy concerned an appeal to the State Supreme Court following a lower court decision discussed by Healey in a recent article in *Connecticut Medicine*.⁴

Our policy statement, which is reproduced in full below, emphasizes for physicians the following:

1. treatment decisions must be based on medical necessity and appropriateness;
2. treatments of no benefit should not be provided;
3. the patient is free to choose or to refuse a treatment or intervention; when the patient is not competent to make a choice, a substituted judgment by an appropriate party is valid.
4. Even if irreversibly ill, the patient should receive therapy, if needed, for physical and mental comfort.

Even as more precise scientific knowledge and new technical advances will change future medical practices, so too will clinical ethical issues continue to evolve. These guidelines are transient expressions that need to be reexamined in the years ahead.

Policy Statement Care of Irreversibly Ill Patients

1. A physician's treatment decisions on behalf of ill patients should be medically appropriate based on knowledge, skill, experience and judgment of what will improve the patient's health and prognosis and make the patient

physically and psychologically comfortable.

- a. In the case of an irreversibly ill patient where a physician determines, after appropriate consultation with other involved health professionals, that intervention is of no benefit in having no likelihood of improving prognosis or restoring health, there should be no obligation to provide or continue artificial life support.
- b. It is therefore appropriate to withhold or remove life-supporting treatments including enteral or parenteral nutrition or hydration in irreversible illness. When the patient, family, and the physician chosen to be the primary health care provider are considering such a step, it should be preceded by a clear explanation of prognosis, alternative treatments and the recognition that the patient's wishes are paramount.
- c. There is an obligation to provide comfort and freedom from pain even while withdrawing life-support efforts that have no chance to alter prognosis.

2. The Chapter supports the considerable legal and ethical opinion that a patient has a common law and constitutional as well as medical ethical right to accept or to reject medical therapy, including life-sustaining care. This freedom of choice includes the specific treatment of artificial provision of food and fluid.

- a. Treatment decision should involve the physician and the patient. When the patient has indicated, as in a living will, a clear preference for not sustaining life by artificial means, that preference should be recognized. In the absence of a written document, the substituted judgment of the patient's choice should be honored.
- b. When the patient has not clearly indicated a choice about life-sustaining medical treatment, decisions are more difficult. Still, the key issue is the individual's right of freedom to make treatment choices as a matter of law and medical ethics.
- c. Therefore, treatment decisions on behalf of incompetent or non-communicative irreversibly ill persons (e.g., in a persistent vegetative state) should be made according to the best available evidence of the patient's preferences.

Adopted at annual meeting, Connecticut Chapter A.C.P., October 21, 1988.

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Are Physicians Meeting the Needs of Their Adolescent Patients?

ARIC SCHICHOR, M.D., MARY KELLY LOMBARDO, LEONARD I. BANCO, M.D.,
AND ROBERT A. KRAMER, M.D.

CONCERNS for the rising death rate for adolescents and young adults compared to the diminishing mortality rate for the overall U.S. population between 1960 and 1980¹ have prompted many health professionals to examine critically the needs of contemporary adolescents. The Robert Wood Johnson Foundation, by major research support, addressed the health needs of high-risk youth between 1982 and 1986.² The Foundation identified the following high-risk factors for this population: venereal disease, teenage pregnancy, alcohol and drug abuse, accidents, homicide, suicide, and mental illness. Subsequent years have seen additional local and national programs address many of these problems. The American Academy of Pediatrics has increased the age range for the population served by its members from 18 to 21 and has encouraged its members to become more involved in the care of adolescents.³ The Accreditation Council for Graduate Medical Education has revised Special Requirements for Internal Medicine Programs to include "experience in caring for adolescent patients."⁴ Nationally, recent efforts have targeted the development of comprehensive school-based health centers, programs to prevent teenage pregnancy, and antidrug abuse campaigns.

In 1985, Connecticut's Capital Area Health Consortium Task Force on Adolescent Medicine began to assess the need for adolescent health services and the availability of such services in North Central Connecticut. Questionnaires were sent to all the members of the Hartford County Medical Association. Data were gathered regarding services provided for adolescents and continuing education interests in adolescent medicine. Separate questionnaires were given to students at suburban Hartford County schools regarding their health concerns and sources of support for these concerns. This

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study reports the results of these surveys and compares the perceived health concerns of the adolescents with the available services provided by the physicians.

Methods

The physicians' questionnaire was mailed out on two occasions to all the members of the Hartford County Medical Association. Data collected included medical specialty, number of years in practice, sex, training in adolescent medicine, and the average number of adolescent patients seen weekly. Physicians were asked to identify services they were providing to address the health issues and risk factors listed in Table 1. The physicians were also asked to note any continuing educational interests they may have which relate to these topics.

The adolescents' questionnaire was given to two suburban school systems with the request to have these questionnaires administered to as many middle and high school students as possible. The students were asked to state their age, grade, sex, and source of health care. They were provided with a checklist of issues and possible concerns (Table 2) and were asked to note those items about which they had worries, questions, or problems. These students were also asked to indicate the sources of help they used (Table 3) for each identified worry, question, or problem.

All questionnaires were completed anonymously. Data from these two questionnaires were compiled and analyzed separately. Final results of the physicians' and students' data were compared in an effort to obtain a better understanding of available services, perceived needs, and potential topics for continuing medical education.

Results

Physicians' Survey:

Questionnaires were sent to all members of the Hartford County Medical Association but only those returned by physicians in active practice were analyzed. Of 1,350 such physicians, 314 (23%) returned the questionnaire. One hundred seventy-two (55%) of the responding practicing physicians indicated that they provided general

Table 1
Health Issues of Adolescents

General Health Maintenance	Sports Medicine
Pregnancy	Suicide
Family Planning	Depression
Abortion	Sexually Transmitted Disease
Drug Abuse	Eating Disorders
Alcohol Abuse	School Problems
Accidents	Adjustment Reaction
Homicide	Chronic Illness
Parenting of Adolescents	Pubertal Development
Rape	Child Abuse

health maintenance to adolescents. Fifty-three percent of the male physicians compared to 59% of the female physicians provided such care. The percentage of physicians providing this care did not vary significantly by the number of years in practice. The majority of these services were provided by primary care physicians (Figure 1), yet fewer than 40% of these physicians had ever received training specific to adolescent medicine. The sources for the training received included: 30% medical school, 62% residency, and 52% continuing education programs.

Table 2
Concerns of Adolescents

General Health	Feeling Down
Pregnancy	Wanting to End It All
Your Weight	V.D.
Getting High	Your Looks
Drugs/Alcohol	Sleeping at Night
Getting Hurt	School
Hurting Someone	Making Friends
Problems with Parents	Acne
Rape	Sports Medicine

The physicians providing primary health care adolescents contributed two thirds of all health care for adolescents in this survey. The average number of adolescents seen in a given week was 20; more than half of these physicians provided treatment for acne, sexually transmitted diseases, sports medicine problems, and issues of pubertal development. Fewer than 50% addressed such topics as eating disorders, chronic illness, drug and alcohol problems, school problems, adjustment reactions of adolescence, accidents, pregnancy prevention and planning, depression, and issues of parenting of adolescents. Further, less than 30% of these physicians acknowledged dealing with issues of abortion, child abuse, rape, suicide, and homicide.

Table 3
Sources of Help for Adolescents

School Counselor	Parent/Relative
Doctor	Religious Leader
School Nurse	School Psychologist
Teacher	No One
Coach	Other
Friend	

Obtaining drug and alcohol abuse information was most often noted as the continuing education interests of the physicians providing general health maintenance to adolescents. More than 25% expressed an interest in con-

Percentage of Physicians in Identified Specialty Providing General Health Care to Adolescents

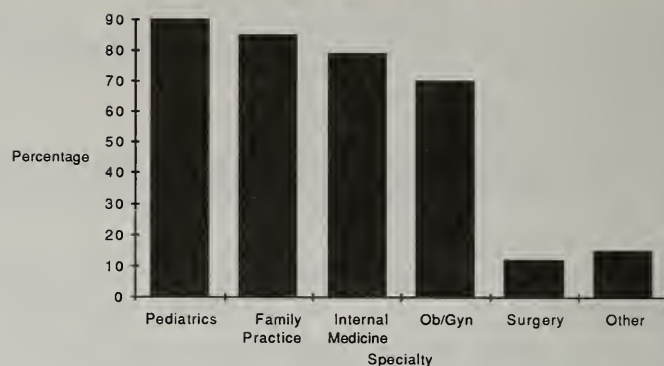


Figure 1

tinuing education in topics related to eating disorders, parenting of adolescents, sports medicine, depression, school problems, and adjustment reactions of adolescents.

Students' Survey:

Each of the two suburban school systems were given 350 questionnaires of which 254 (73%) were completed in one and 137 (39%) in the second school system. Respondents were 55% female and ranged in age from 11 to 18, with a mean age of 13.4 years. The majority of these students were in seventh grade (60%), with the remaining grades having lesser representation: eighth grade-5%, ninth grade-12%, tenth grade-19% and eleventh grade-4%.

The most common problems checked, by order of frequency, related to: school (24%), appearance (23%), parents (20%), weight (20%), and general health (19%). Females were more likely (1.6:1) to note concerns than were males. The nature of the concerns also differed between the sexes, with females being concerned about appearance issues and males being concerned about sports injuries or getting hurt (Table 4). Both sexes showed a similar concern about school and problems with parents.

Table 4
Most Common Issues Identified by Adolescents

Males	Females
School	Your Looks
Sports Injuries	School
Feeling Down	Your Weight
Problems with Parents	Problems with Parents
Getting Hurt	General Health

A second analysis of data was carried out by clustering the adolescents into two age groups, those less than or equal to 14 years (early adolescence) and those greater than 14 years (middle and late adolescence). Although the number of responses per adolescent (2-1/2) was consistent in both groups, the type of concerns identified differed in each group (Table 5). The early adolescents focused on appearance and general health, while the older adolescents indicated concerns about feelings and relations with school and parents. Both groups used friends and relatives as the primary source of help for their problems. Early adolescents consulted their physicians for help with concerns relating to general health,

Table 5
Most Common Issues of Early Adolescents
and Middle/Late Adolescents

<i>Early Adolescents</i>	<i>Middle/Late Adolescents</i>
Your Looks	School
General Health	Problems with Parents
Your Weight	Feeling Down
School	Getting Hurt
Sports Injuries	Your Looks

weight, and sports injuries, while the middle and late adolescents rarely identified their physicians as sources of help, except for acute medical problems resulting from physical injuries.

Discussion

Although only one of every two physicians who answered the questionnaire provides general health care to adolescents, these physicians tend to provide the major portion of all health care to the adolescents seen by all the physicians. At least three quarters of the physicians in each of the four primary care disciplines saw themselves as providing this type of care. These findings indicate a rather broad based interest among these physicians to provide health care to adolescents.

Fewer than half of these physicians providing general health care to adolescents deal with issues which relate to risk taking behavior or which involve psychosocial factors. An even smaller number of these physicians deal with problems of adolescents which may have legal implications.

The adolescents indicated that medical problems may be on their minds, but are often mixed in among a number of other psychosocial issues. This is consistent with the belief of invulnerability felt by many adolescents combined with the fact that most often these adolescents are generally in good health. The utilization of health care professionals is of low priority to these adolescents who identify relatives or friends as their primary source of help for their problems.

The validity of the findings in this study is limited by the low response rate by both the physicians and the adolescents. The specific geographic distribution of the physicians answering the questionnaires is also unknown. Health concern data were derived only from a suburban population consisting mostly of early adolescents. Despite these limitations, certain trends do emerge from these data. Physicians tend to be more comfortable dealing with medical issues of adolescents such as acne, sexually transmitted diseases, pubertal development, and sports injuries. Early adolescents tend to be more concerned about such medical issues and also seem to be more likely to seek help from physicians for such issues. Hence, the best entrée for physicians interested in working with adolescents is the early adolescent. It is suggested

that the physicians who are successful in getting the adolescent to come in for care will have to deal with other than medical issues if they would like to follow their adolescent patients over time. According to the physicians who provide primary care to adolescents, it is clear that they understand that through continuing education they have to expand their skills in the psychosocial areas of adolescent health. Such skills will allow these physicians to make the transition from dealing with issues of appearance and general health expressed by the early adolescents to issues of relations to parents, peers, and school expressed by older adolescents. When these physicians become resources for the mid-and late adolescents, they can begin to address the kinds of behavior which have the potential to cause increased morbidity and mortality in this age group.

In summary, it is encouraging to see that there is a sizable number of primary care physicians who are interested in providing general care to adolescents. It is also clear that the early adolescents are the most likely segment of that age group to make use of such care. The unanswered question is how to keep those adolescents coming for care as they get older. Adolescents have to perceive that the physicians have something to offer to them. The challenge to the academic community and to adolescent medicine specialists is to coordinate the resources, seminars, and training which enable physicians to address the needs of mid-and late adolescents. It would also be helpful to determine the geographic distribution of these physicians by asking for the zip code of the area which they serve. Additional information regarding the health concerns of the urban adolescents would also be useful. The Connecticut Capital Area Health Consortium Task Force on Adolescent Medicine in conjunction with the Hartford County Medical Association, the Connecticut Chapter of the American Academy of Pediatrics, and the University of Connecticut School of Medicine could help to obtain the needed additional data and assist in the identification and development of resources and ongoing forms on adolescent health. Involvement by similar professional societies in internal medicine, family practice, and obstetrics and gynecology would be welcomed and very beneficial.

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Risks Associated with Human Parvovirus B19 Infection

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THIS report was developed to assist physicians, public health officials, and other health-care professionals respond to public concerns about recently recognized, serious complications of human parvovirus B19 (B19) infection, including transient aplastic crisis (TAC), chronic anemia, and fetal death. It includes background information about the virus, clinical manifestations, pathogenesis, epidemiology, and diagnostic testing. In addition, interim guidelines are presented for preventing B19 infection, managing persons exposed to persons with B19 infection, and managing patients infected with B19. These guidelines reflect both the current limited information about the extent to which B19 infection leads to severe complications and the limited availability of diagnostic testing. Priorities for future research are identified.

General Information

B19 was discovered in England in 1975 in serum specimens from healthy blood donors.¹ Since its discovery, B19 has been shown to be the causative agent of erythema infectiosum (EI) (also known as fifth disease) and is the primary etiologic agent of TAC in patients with chronic hemolytic anemias.²⁻⁴ B19 has also been associated with fetal death (both spontaneous abortions and stillbirths), acute arthralgias and arthritis, and chronic anemia in immunodeficient patients.⁵⁻¹⁴

The virus belongs to the family *Parvoviridae*, which includes two genera of vertebrate viruses: genus parvovirus (autonomously replicating parvoviruses) and genus dependovirus (parvoviruses that require a helper virus, such as adenovirus or herpes virus, for replication); and one genus of invertebrate viruses, the genus densovirus.¹⁵ B19 is in the genus parvovirus, which includes a number of animal parvoviruses such as the canine parvovirus and feline panleukopenia virus. The parvoviruses tend to be species-specific; only the adeno-associated parvoviruses (members of the dependovirus genus) and B19 are known to infect humans. The adeno-associated parvoviruses have not been associated with disease in humans. Fecal parvoviruses and the RA1 virus have been reported but

not confirmed to be human pathogens.^{16,17} B19 is a heat-stable virus and can survive at 60°C (140°F) for up to 12 hours.

Clinical Features of B19 Infection

Erythema Infectiosum (Fifth Disease)

The most commonly recognized illness associated with B19 infection is EI. EI is a mild childhood illness characterized by a facial rash ("slapped cheek" appearance), and a reticulated or lacelike rash on the trunk and extremities.¹⁸ Reappearance of the rash may occur for several weeks following nonspecific stimuli such as change in temperature, sunlight, and emotional stress. Typically, the patient is otherwise well at rash onset but often gives a history of mild systemic symptoms 1-4 days before rash onset. In some EI outbreaks, pruritis has been a common clinical feature. In addition to typical EI, B19 infection has been associated with a variety of other exanthems, including those that are rubella-like, vesicular, and purpuric.¹⁸

Asymptomatic Infection

In outbreak investigations, asymptomatic infection has been reported in approximately 20% of children and adults.^{19,20}

Arthropathy

In some outbreaks of EI, arthralgias and arthritis have been commonly reported.^{7,8,21} Infection may produce a symmetrical peripheral polyarthropathy. Joints in the hands are most frequently affected, followed by the knees and wrists. Symptoms are usually self-limited but may persist for several months. Joint symptoms, more common in adults, may occur as the sole manifestation of infection.

Transient Aplastic Crisis and Severe Anemia

B19 is the primary etiologic agent causing TAC in patients with chronic hemolytic anemias (e.g., sickle cell disease, hemoglobin SC disease, hereditary spherocytosis, β -thalassemia, and autoimmune hemolytic anemia).^{22,23} It can also cause TAC in other conditions in which increased red cell production is necessary to maintain stable red cell indices, as may occur in anemia due to blood loss. Patients with TAC typically present with pallor, weakness, and lethargy and may report a non-

specific prodromal illness in the preceding 1-7 days. Few patients with TAC report a rash. In the acute phase of the illness, patients usually have a moderate to severe anemia with absence of reticulocytes, and bone marrow examination shows a hypoplastic or an aplastic erythroid series with a normal myeloid series. Recovery is indicated by a return of reticulocytes in the peripheral smear approximately 7-10 days after their disappearance. TAC may require transfusion and hospitalization and can be fatal if not treated promptly.

B19 Infection in Immunodeficient Patients

A B19-related severe chronic anemia associated with red cell aplasia has been described in patients on maintenance chemotherapy for acute lymphocytic leukemia, patients with congenital immunodeficiencies, and patients with human immunodeficiency virus (HIV)-related immunodeficiency.⁹⁻¹⁴ It is not yet known how often B19 causes chronic anemia in immunodeficient patients or which patients are most susceptible to this complication of infection. Chronic B19 infection should, however, be included in the differential diagnosis of chronic anemia in the immunodeficient patient.

Infection in the Pregnant Woman

Intrauterine infection and fetal death

In most of the reported B19 infections occurring during pregnancy, the fetus has not been adversely affected.^{5,6,24-30} However, in some cases B19 infection has been associated with fetal death. The risk of fetal death attributable to parvovirus infection following documented maternal infection (B19 IgM-antibody-positive) is not known, but preliminary results of one study from the United Kingdom suggest that it is <10% (30; SM Hall, unpublished data). In that study, 174 pregnant women with IgM antibody to B19 were followed prospectively to delivery. Fetal loss occurred in 30 (17.2%): 21 (19.1%) of 110 women infected during the first 12 weeks of pregnancy, seven (15.2%) of 46 women infected during weeks 13-20, one (6.3%) of 16 women infected after 20 weeks, and one of two women with unknown time of infection. Fetal death most commonly occurred from the 10th through the 20th weeks of pregnancy. Not all fetal deaths directly resulted from B19 infection. Since this study did not include a control group, the number of deaths attributable to B19 infection cannot be calculated directly. In other studies, rates of recognized pregnancies ended in spontaneous abortions from all causes by 28 weeks' gestation range from 10% to 25%.³¹ In the British study, the number of fetal deaths linked to B19 infection can be estimated by determining whether fetal tissues contain B19 DNA. Tissues from 14 fetuses were tested for B19 DNA: six were positive, two were equivocal, and six were negative. The cause of death is likely to have been B19 infection for the DNA-positive fetuses; thus, at least six (3.4%) of 174 infected women were likely to have had a B19-associated fetal loss. When the results of the 14 tested were extrapolated to all 30 fetal deaths, an estimated 17 fetuses would be B19 DNA-positive or equivocal,

suggesting that ≤ 17 ($\leq 9.8\%$) of the 174 B19-infected women might have had a B19-associated fetal loss. Antibody studies of liveborn infants and hybridization studies of fetal tissues indicate that less than one third of maternal infections are associated with fetal infection in this study.

Results from an ongoing study in the United States also suggest that B19-attributable fetal deaths are infrequent (CDC, unpublished data). In this study, 95 pregnant women with IgM antibody to B19 are being followed prospectively. Fetal loss has so far occurred in two (4.1%) of 49 women followed to term. It is not known whether the two fetal deaths were caused by B19 infection. One fetus was hydropic; the other was not described. No tissues from either fetus were available for B19 hybridization studies.

When the antibody status of the woman is unknown, estimates of the risk of fetal death after exposure must take into account the rate of susceptibility in the population and the risk of infection after the exposure. For example, by taking these factors into account, the *upper limit* estimate of the risk of fetal death would be <2.5% after exposure to household members with documented infection (<0.1 risk of fetal death $\times 0.5$ rate of susceptibility $\times 0.5$ rate of infection $\times 100$; see sections on Epidemiologic Features of B19 Infection: Prevalence and Transmission) and <1.5% after prolonged exposure at schools with widespread EI among students (<0.1 risk of fetal death $\times 0.5$ rate of susceptibility $\times 0.3$ rate of infection $\times 100$). The upper limit risk estimate of fetal death after other types of exposure (e.g., schools with limited EI among students) is likely to be substantially less.

A study of 96 women who had stillbirths, 96 women who had spontaneous abortions, and controls matched by age, duration of pregnancy, and location suggests that B19 is not responsible for a substantial proportion of fetal deaths in the general population.³² In this study, the rate of serologically confirmed B19 infection was the same (1%) in cases and controls. In a survey of 50 fetuses with nonimmunologic hydrops fetalis, an uncommonly diagnosed cause of fetal death, four (8%) were positive for B19 DNA.²⁵

Congenital anomalies

Since some of the animal parvoviruses are teratogens,³³ the possibility that infection may also be associated with congenital anomalies in humans is a concern. However, there is no evidence that the rate of congenital anomalies following B19 infection exceeds background rates. B19-associated congenital anomalies have not been reported among several hundred liveborn infants of B19-infected mothers. One aborted fetus with eye anomalies and histologic evidence of damage to multiple tissues born to a B19-infected woman has been reported.³⁴ An anencephalic fetus was reported in a B19-infected woman, but the timing of infection made it unlikely that B19 contributed to the defect.³⁵

Pathogenesis

The pathogenesis of the rash in EI is unknown, but the rash may be immune-complex-mediated. The other, more serious manifestations of B19 infection are related to the propensity of the virus to infect and lyse erythroid precursor cells and interrupt normal red cell production.³⁶ In a person with normal hematopoiesis, B19 infection produces a self-limited red cell aplasia that is clinically inapparent. Transient leukopenia, lymphocytopenia, and thrombocytopenia have also been reported with B19 infection in the normal host.^{37,38}

In patients who have increased rates of red cell destruction or loss and who depend on compensatory increases in red cell production to maintain stable red cell indices, B19 infection may lead to TAC. Patients at risk for TAC include those with chronic hemolytic anemias and those with anemias associated with acute or chronic blood loss. In immunodeficient persons, B19 infection may persist, causing chronic red cell aplasia, which results in chronic anemia; chronic neutropenia has also been described.¹⁰

B19 DNA-positive tissues have been reported in 20 fetal deaths; in all 17 cases in which pathologic findings were described, the fetuses had nonimmunologic hydrops fetalis.^{6,25-27,30,35,39-44} The precise pathogenesis of fetal death remains unclear. Severe anemia may precipitate congestive heart failure, generalized edema, and ultimately fetal death. The fetus may be particularly vulnerable to B19 infection because red cell survival is short, and the red cell volume is rapidly expanding. Severe anemia, B19 viremia, and cytologic changes in erythroid precursor cells have been described in fetuses just before death.^{26,27,39} Chronic infection may occur in the fetus (one fetus was viremic for at least 4 weeks).²⁶ In one case report, infection of myocardial cells was noted, suggesting that direct damage to myocardial tissue may also contribute to the disease process in the fetus.²⁹

Epidemiologic Features of B19 Infection

Prevalence

B19 infection occurs worldwide.^{45,46} Infection with B19 can occur throughout the year, in all age groups, during outbreaks of EI, or as sporadic cases. B19 infection is most frequently recognized during outbreaks of EI in schools. These outbreaks often begin in late winter or early spring and may continue until school recesses for the summer. The level of EI activity in a community varies from year to year; periods of increased activity lasting several years are generally followed by several years of decreased activity.⁴⁷⁻⁵⁰ The reported seroprevalence ranges from 2% to 15% in children 1-5 years old, 15% to 60% in children 5-19 years old, and 30% to 60% in adults.^{18,40,51,52}

Incubation Period

Studies of secondary illness in households suggest that the incubation period for clinical EI and TAC is usually 4-14 days but can be as long as 20 days.¹⁸ In volunteer

studies, rash illness occurred 17-18 days after inoculation.^{37,38}

Transmission

B19 DNA has been found in respiratory secretions in viremic patients, which suggests that these secretions are involved in transmission.^{19,20,37} In studies of human volunteers, serum and respiratory secretions became positive for B19 DNA 5-10 days after intranasal inoculation (during the prodromal illness).^{37,38} By the time of onset of rash or arthralgia, serum specimens had been negative for 1-5 days. B19 has not been detected in the respiratory secretions and only rarely in the serum of patients after onset of EI.³⁷ In contrast, acute serum specimens are often positive for B19 DNA in patients when they present with TAC; serum specimens are usually negative by 7 days after onset of illness.⁵³ The presence of B19 DNA in serum or respiratory secretions presumably correlates with infectiousness; thus, patients with EI are probably past the period of greatest infectiousness, while patients with TAC are likely to be infectious during the course of their illness.

The presence of IgG antibody correlates with a lower risk of infection. This decreased risk has been suggested in volunteers who were experimentally inoculated with B19: four of five IgG-negative but only one of four IgG-positive volunteers developed serologic evidence of infection.³⁷ The IgG-positive volunteer who became infected had low levels of IgG antibody before challenge and had a lower titer and shorter duration of viremia than had the four infected volunteers who were IgG-negative.

The virus is transmitted effectively after close contact exposures. The secondary attack rate for infection among susceptible household contacts of patients with TAC or EI is about 50%.^{19,20} In school outbreaks, 10%-60% of students may develop EI. In outbreaks in which student involvement is widespread, preliminary data suggest 20%-30% of susceptible (IgG-antibody-negative) staff may develop serologic evidence of B19 infection during the course of the outbreak (CDC, unpublished data).

In outbreak settings, it is not known whether the primary mode of transmission involves direct person-to-person contact, fomites, large-particle droplets, or small-particle droplets. The virus can also be transmitted parenterally by transfusion of blood or blood products and vertically from mother to fetus.^{1,54,55} Transmission rarely occurs during transfusion with single-donor blood products but is common during treatment with clotting-factor concentrates, even after steam- or dry-heat treatment of the clotting factor concentrate.^{1,54,55} Tattooing was suspected as the source of B19 transmission in two instances.⁵⁶

Diagnosis

B19 Antibody Assays

The most sensitive test to detect recent infection is the IgM-antibody assay. B19 IgM antibody can be detected by capture-antibody radioimmunoassay or enzyme im-

munoassay in approximately 90% of cases by the third day after symptoms of TAC or EI begin.^{57,58} The titer and the percentage of positives begin to decline 30-60 days after onset. B19 IgG antibody is usually present by the seventh day of illness and persists for years. B19 antibody may not be detectable in immunodeficient patients with chronic B19 infection, and additional testing for B19 DNA or viral antigens may be necessary to document infection.

B19 has not been grown in standard cell culture systems or animal model systems, but it has been grown in bone marrow explant culture systems.⁵⁹ The inability to grow the virus in sufficient quantity to produce antigen for diagnostic assays has precluded widespread availability of B19 testing.^{36,60,61} Recently parvovirus B19 DNA has been incorporated into the genome of a Chinese hamster ovary cell line.⁶² This cell line expresses B19 capsid proteins as noninfectious virion-like particles that can be used as an antigen for antibody assays; this source of antigen should lead to increased availability of diagnostic tests.

Assays for B19 DNA

The most sensitive test for detecting the virus is nucleic acid hybridization.^{63,64} This test has been used to identify B19 DNA in serum, leukocytes, respiratory secretions, urine, and tissue specimens. One group reported that B19 DNA was more likely to be detected in leukocytes than in serum.⁶⁵

Histologic Features of B19 Infection

Light and electron microscopy can be helpful in diagnosing B19 infections.^{1,23,41} By light microscopy, eosinophilic nuclear inclusions with peripheral condensation of chromatin can be seen in erythroid precursor cells of infected patients. The inclusions contain parvovirus-like particles by transmission electron microscopy.^{28,41,66} B19-like particles may also be seen in electron microscopy in serum specimens of some infected patients.^{1,23,41} Histologic findings in fetal tissues also may include a severe leukoerythroblastic reaction and excessive iron deposition in tissues, which indicates hemolysis.

Assays to Determine Site of Infection

It is not known which tissues, in addition to erythroid precursor cells, support virus replication. Several tests have been developed that distinguish virus infection of tissue or cells from deposition of virus by passive transfer in blood. In situ hybridization can demonstrate viral DNA in specific cells and has been used to show that B19 sometimes infects fetal myocardial cells.²⁹ Replicative forms of B19 DNA and nonstructural proteins can be demonstrated by Southern and Western blot analysis, respectively, indicating infection in the tissue.^{67,68}

Prevention of Infection

Risk Groups

Although B19 infection usually produces a mild, self-limited illness, three groups of persons are at risk for serious complications of infection: 1) persons with chronic hemolytic anemias, 2) persons with congenital or

acquired immunodeficiencies, and 3) pregnant women. Since infection in these persons can lead to substantial morbidity and some mortality, consideration should be given to preventing or ameliorating disease.

Immunization

Active

There is no vaccine to prevent B19, but a recently developed cell line that expresses B19 capsid proteins as noninfectious virus-like particles has been proposed as a source of antigen for development of a candidate vaccine.⁶²

Passive

No studies have been conducted to determine whether preexposure or postexposure prophylaxis with commercially available immune globulin (IG) preparations would prevent infection or modify the course of illness during community outbreaks. Routine prophylaxis with IG cannot be recommended at this time.

Health-Care Settings

Guidelines for isolation precautions in hospitals have been published for EI,⁶⁹ but recent information suggests that these guidelines should be modified. Most patients with EI are past their period of infectiousness and do not present a risk for further transmission; thus isolation precautions are not indicated. However, there is risk for nosocomial transmission of B19 from patients with TAC and from immunodeficient patients with chronic B19 infection. These patients should be considered infectious and placed on isolation precautions for the duration of their illness or until the infection has been cleared. Nosocomial transmission of B19 has been associated with one case of TAC.⁷⁰ Transmission of B19 infection has also occurred in medical research laboratories.^{4,71}

Patients with TAC or chronic B19 infection should be admitted to private rooms. Persons in close contact with the patients should wear masks. Gloves should be worn by persons likely to touch infective material such as respiratory secretions, and gowns should be worn when soiling is anticipated (contact isolation).⁶⁹ Hands should be washed after the patient or potentially contaminated articles are touched and before care is provided to another patient. B19-infected patients may share a room with another B19-infected patient unless sharing is contraindicated by another infection or condition.

Health-care workers should be advised that they are at risk of B19 infection after exposure in the hospital or in the community and that there may be a risk for further transmission to patients. Routine infection-control practices should minimize the risk of transmission.

Personnel who may be pregnant or who might become pregnant should know about potential risks to the fetus from B19 infection and about preventive measures that may reduce those risks.

Homes, Schools, and Workplaces

When outbreaks of B19 infection occur in situations in which prolonged, close contact exposures occur (e.g., at home, in schools, or in day-care centers), options for

preventing transmission are limited. The greatest risk of transmitting the virus occurs before symptoms of EI develop; therefore, transmission cannot be prevented by identifying and excluding persons with EI. The efficacy of decontaminating toys and environmental surfaces to decrease B19 transmission has not been studied. The efficacy of handwashing to decrease B19 transmission has not been studied either, but handwashing is recommended as a practical and probably effective measure.

When outbreaks occur, parents of school-aged children and employees should be advised about the risk of transmitting and acquiring infection and about who is at risk for serious complications. Persons who wish to obtain additional information about risks and management of B19 exposures should be referred to their health-care provider and state or local health officials.

The decision to try to decrease any person's risk of infection by avoiding a workplace or school environment in which an EI outbreak is occurring should be made by the person after discussions with family members, health-care providers, public health officials, and employers or school officials. A policy to routinely exclude members of high-risk groups is not recommended.

Patient Management

Patients with Chronic Hemolytic Anemia

The exposed patient with chronic hemolytic anemia should be managed by alerting the patient or his/her parents or guardians about the exposure, the symptoms and signs associated with TAC (pallor, weakness, and lethargy), and the need to consult a physician immediately if symptoms or signs of TAC develop. Management of the patient with TAC is based on treating symptoms of the associated anemia and may require blood transfusion.

Patients with Congenital and Acquired Immunodeficiencies

The exposed patient with a congenital or acquired immunodeficiency should be managed by advising the patient or his/her parents or guardians about the exposure and the possibility that B19 infection may lead to chronic anemia. The physician should consider B19 infection in the differential diagnosis of chronic anemia in this group of patients, especially if there is an outbreak of EI in the community.

In several patients with acute lymphocytic leukemia, the administration of IG resulted in disappearance of viremia and improvement in red cell indices.¹⁰ In other patients, the infection and associated anemia resolved when immune function returned.^{12,14} The role of IG in the treatment of these patients needs further study.

Pregnant Women

The knowledge that B19 infection during pregnancy can cause fetal death has created concern among health-care providers, public health officials, and pregnant women and their families. In managing exposed preg-

nant women, risks should be considered in the context of other risks to the pregnancy and the risks associated with intervention.

For women with a documented infection, maternal serum α -fetoprotein levels and diagnostic ultrasound examinations have been used to identify adversely affected fetuses, but the sensitivity and specificity of these tests, their appropriate timing, and the risks and benefits of their use in managing infected pregnant women have not yet been determined.^{39,41} Interpretation of the ultrasound is difficult early in pregnancy and should be supervised by a physician experienced in diagnosing fetal abnormalities. Intrauterine blood transfusion (IBT) has been proposed as treatment for the fetus with B19-induced severe anemia. However, IBT is a high-risk, specialized procedure of unproven benefit in this situation and cannot be recommended for routine treatment of B19-related hydrops fetalis.⁷²

Availability of Diagnostic Testing at CDC

Diagnostic testing is available at only a few sites, primarily research laboratories; increasing the availability of diagnostic testing is a public health priority. The Division of Viral Diseases, Center for Infectious Diseases, CDC, can accept a limited number of specimens for B19 diagnostic testing. At this time, CDC is accepting specimens through state health departments from patients with TAC, immunodeficient patients with chronic anemia, pregnant women exposed to B19 or with symptoms suggestive of B19 infection, and cases of nonimmune fetal hydrops possibly related to B19 infection, and not accepting specimens for routine antibody testing. Physicians can arrange testing at CDC by consulting their state health department.

Priorities for Future Research

The following areas have been identified as high priorities for future public health-related research on B19 infection:

1. Develop surveillance methods that distinguish outbreaks from sporadic disease.
2. Refine estimates of infection rates following exposures in the home, the workplace, and school.
3. Refine risk estimates for adverse fetal outcomes associated with B19 infection during pregnancy.
4. Evaluate methods to treat and prevent B19-related fetal hydrops.
5. Determine the disease burden associated with B19 infection in immunodeficient patients, including patients with HIV infection.
6. Determine the risk of infection and factors associated with transmission in health-care settings.
7. Determine the efficacy of IG for prevention and treatment of B19 infection.
8. Determine the potential reduction in morbidity and mortality associated with development and use of a B19 vaccine.

Reported by: Div of Reproductive Health, Center for Chronic Disease Prevention and Health Promotion; Div of Immunization, Center for Prevention Svcs; Div of Birth Defects and Developmental Disabilities, Center for Environmental Health and Injury Control; Div of Surveillance and Epidemiologic Studies, Epidemiology Program Office; National Institute for Occupational Safety and Health; AIDS Program, Hospital Infections Program, Div of Host Factors, Div of Viral Diseases, Center for Infectious Diseases, CDC.

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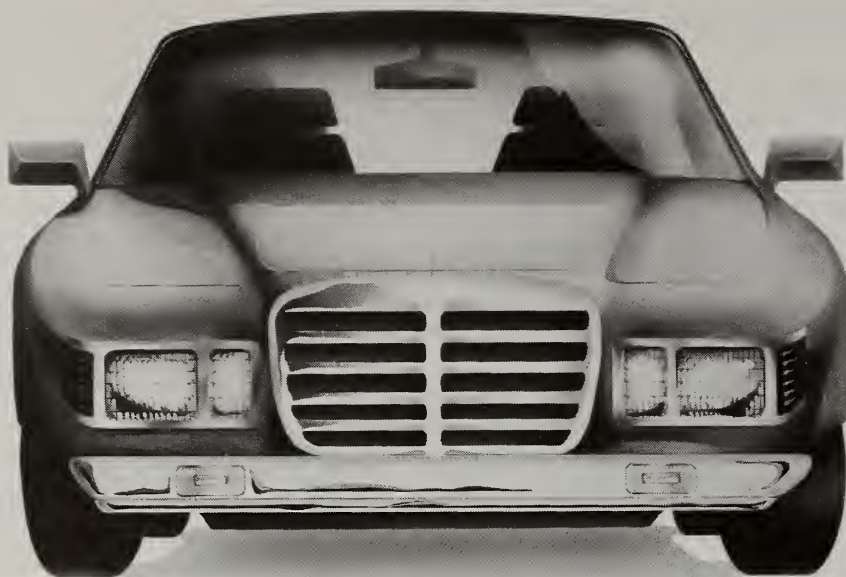
AMA Prepares Comprehensive Report On Recent Aids Legislation

California, New York, Ohio, Missouri, and Connecticut have all recently enacted legislation that either defines infectious waste or determines its legal disposal process. Meanwhile, Illinois has created two exceptions to its written informed consent law in order to protect health care workers who may accidentally come into contact with a patient infected with human immunodeficiency virus (HIV).

These are but two examples of legislation passed last year by states attempting to cope with the growing AIDS epidemic. The comprehensive efforts of the nation's legislative battle against AIDS can be found in *AIDS: 1988 State Legislative Update*, the second in a legislative monograph series, that compiles and categorizes the most recent laws concerning key aspect of the AIDS epidemic.

Beginning with a brief overview on the public health issues, *AIDS: 1988 State Legislative Update* quickly shifts from testing, criminality, and confidentiality, to the advertising of home testing kits, discrimination, and ethical obligations, with several stops covering the issues in between.

AIDS: 1988 State Legislative Update is being offered to AMA members for \$31.95; the regular price is \$39.95.



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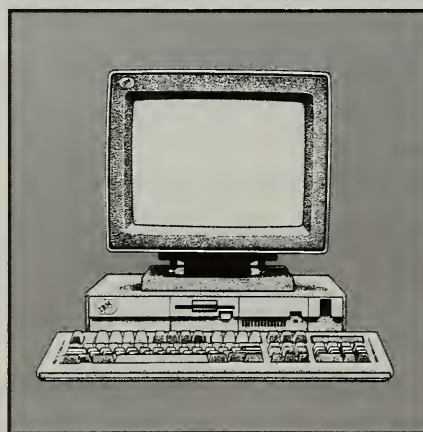
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Physician Need

An Alternative Projection From a Study of Large, Prepaid Group Practices

ROBERT MULHAUSEN, M.D. AND JEANNE McGEE, PH.D.

To model a base level of physician demand in a managed health care system, we examined in 1983 the ratios by specialty of full-time equivalent physicians to health maintenance organization members in seven large, closed-panel health maintenance organizations, each with more than 100,000 members. The medical director of each plan was surveyed by mailed questionnaire and telephone interview to determine the plan's number of full-time equivalent physicians by specialty and members served. Out-of-plan physicians contracted by the group were included within the specialty distribution wherever possible. We compared our findings (4,779.4 full-time equivalent physicians serving 4,297,790 members) with Graduate Medical Education National Advisory Committee and others' projections of physician need and supply. Based on this model and unknowns that might affect utilization, our study suggests that at least 111 physicians per 100,000 population would be necessary in a system that emphasized reduced utilization of services and that more primary care physicians would be needed than the Graduate Medical Education National Advisory Committee predicted would be available.

IN 1980, the Graduate Medical Education and National Advisory Committee (GMENAC) issued a landmark study that projected US physician supply and need in the year 1990 and beyond.¹ The GMENAC forecast of a significant future surplus of physicians was essentially reconfirmed for 1990 by a recent US government study.² Since 1980, the socioeconomic environment in which medicine is practiced in the United States has changed significantly, making reexamination of the GMENAC projections timely. With the recognition that competition and marketplace strategies have failed to contain

rapidly rising health care costs, policymakers have begun to call again for increased governmental regulation of health care. Indeed, predictions of some form of nationalized health insurance are once again receiving attention.³

The physician-need projections made by the GMENAC, which assumed easy access to physician services, may miss the target significantly as we move toward a more controlled health care environment. Recognizing the substantial difference in utilization patterns between prepaid and fee-for-service systems, we examined physician distribution in seven large, closed-panel health maintenance organizations (HMOs) as a model for estimating the number of physicians by specialty that might be required in an extensive system of managed health care services.

We put this model forth not as an ideal, but as an example of the number of physicians needed, by specialty, to serve the health needs of our population under a system that attempts to control health care resources. As with any model, there are caveats for interpretation. There is a certain amount of out-of-plan utilization in HMOs (estimated at 2% to 5%) that is not reflected in our data. Assuming a selection bias by persons who are healthier than average, our model probably underestimates the number of general and specialty physicians needed. Likewise, HMOs have traditionally not paid for elective, non-essential services such as certain types of plastic surgery procedures, and they have had restrictive benefits for chronic mental illnesses. Hence, we would also expect that our model underestimates the need/demand for specialists, especially psychiatrists. Physicians who engage in medical education and research are also not reflected in this model. However, even if the physician utilization experienced by the studied plans were significantly inflated to account for these and other factors, the resulting use rate would still be significantly below the GMENAC projections for both need and availability.

Methods

Large, prepaid group plans (with > 100,000 enrollees)

From Interstudy, Excelsior, Minn (Drs Mulhausen and McGee); Department of Medicine, St. Paul-Ramsey Medical Center, St Paul, Minn (Dr Mulhausen); and University of Minnesota Medical School and School of Public Health, Minneapolis (Dr. Mulhausen). Dr McGee is currently president of Research Insights, Inc, Excelsior, Minn.

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were chosen for the study to maximize the breadth of physician specialties and the numbers of physicians in each specialty. The seven HMOs we surveyed are among the oldest and largest in the country. Each is affiliated with the Kaiser Permanente System. Ranging in size from 113,358 to 1,834,743 members, these HMOs served a combined total of 4,297,790 members in 1983. Although our sample of seven HMOs represented less than 3% of all HMOs in 1983, these HMOs collectively accounted for 34% of total national HMO enrollment in December of that year.⁴ Each HMO studied is a closed-panel practice plan with a relatively stable physician group, providing an ideal model for calculating ratios of full-time equivalent physicians relative to a patient base composed exclusively of HMO members.

Table 1.—Full-time Equivalent Physicians (MD and DO) per 100,000 Population: Estimates of Need and Supply for Years 1983, 1990, and 2000*

Estimate of Physician Need by Study				
	Current Study, 1983	HEW, ⁵ 1990	GMENAC, ¹ 1990	GMENAC, ¹ 2000
Study type	HMO only	Adjusted for prepaid plans	Unadjusted for prepaid plans	Unadjusted for prepaid plans
No. of physicians	111	170	191	191
Estimate of Physician Supply by Study				
	AMA, ⁶ 1983	GMENAC, ¹ 1990	GMENAC, ⁷ 1990	GMENAC, ⁷ 2000
Study type	Actual†	Unadjusted for prepaid plans	Unadjusted for prepaid plans (revised)	Unadjusted for prepaid plans (revised)
No. of physicians	158	220	220	233

*HMO indicates health maintenance organization; AMA, American Medical Association; GMENAC, Graduate Medical Education and National Advisory Committee; and HEW, Department of Health, Education, and Welfare.
†See text.

A questionnaire was prepared and sent to seven Kaiser Permanente HMOs located in Los Angeles and Oakland, Calif; Washington, DC; Cleveland, Ohio; Denver, Colo; Portland, Ore; and Honolulu, Hawaii. To encourage consistency in reporting, we discussed the questionnaire with medical directors or their designates. We obtained data on the specialty distribution of physicians employed during 1983 expressed as full-time equivalents per 100,000 members of the closed-panel population. There was no standardized definition of "full-time equivalent" other than that used by the individual plans.

To account for total physician use, the number of out-of-plan full-time equivalent physicians contracted by the group are included within the specialty distribution whenever possible. For some plans and some specialties, breakdowns for contract full-time equivalent physicians were not available; in these cases, we report results for a given specialty based on data from those plans that were able to provide complete data for that specialty. Certain of the surgical subspecialties and a small "other" category are included in the aggregate analysis but excluded in the breakdown by specialty due to the small number of full-time equivalent physicians employed. Out-of-plan utilization by enrollees was not determined and was not considered in the presentation of the data.

Results

Estimates of Physician Need and Supply

For the seven HMOs we studied in 1983, there were 111.2 physicians per 100,000 members (4,779.4 full-time equivalent physicians serving a combined HMO mem-

bership of 4,297,790).

Table 1 displays findings from the current study with several well-known projections of physician supply and need expressed as ratios of physicians per 100,000 population. The studies included in this table reflect several approaches to estimating physician need. The current study's staffing ratio and the 1974 Bureau of Health Resources Development, Department of Health, Education, and Welfare projection⁵ both involve data on staffing patterns in prepaid systems. Our study reports the actual staffing in seven large HMOs. The Department of Health, Education, and Welfare study⁵ used data on staffing patterns in group-practice HMOs as part of its projection of physician need across all practice sectors in the United States in 1990. Based on the assumption that 28% of the US population would be enrolled in HMOs in 1990, the Department of Health, Education, and Welfare study estimated that 170 physicians per 100,000 population would be needed in 1990.

Table 1 also shows two global projections of physician need made by the GMENAC. In 1980, the GMENAC estimated an overall need for 191 full-time equivalent physicians per 100,000 for 1990 and for the year 2000. Unlike the Department of Health, Education, and Welfare study, the GMENAC projection did not explicitly take account of the growth of managed health care systems and the distinctive patterns of physician utilization within those systems.

Estimates of physician supply in Table 1 are taken from the American Medical Association,⁶ from the GMENAC,¹ and from Tarlov's article⁷ reporting revised GMENAC projections of physician supply. The American Medical Association reported that there were 482,635 professionally active medical physicians in the United States in 1983. Of these, 423,367 were involved in patient care activities, including 73,171 residents in training. Osteopathic physicians were not included in these numbers.

To compare these supply figures with the projections of need, a few adjustments for equivalence must be made. The GMENAC study counts each resident as 0.35 full-time equivalent physician. Incorporating this correction results in a total of 375,800 full-time equivalent medical physicians who were professionally active in patient care in 1983 [(423,367-73,171) + (73,171×0.35)]. This yields a ratio of 158 medical physicians per 100,000 population in 1983. Equivalent GMENAC data, corrected by deleting numbers of osteopathic physicians and assuming that the ratio of patient care/total physicians (0.86) remains constant from 1983 to 1990, would result in a projected adjusted supply ratio of 181 medical physicians per 100,000 population for 1990. Thus, in 1983, the ratio of medical physicians in active patient care per 100,000 population in the United States was 1.42 times higher than the ratio of physicians per 100,000 in the studied prepaid system in that same year. The adjusted

GMENAC supply projection for 1990 is 1.63 times the 1983 physician use rate in the HMOs studied.

Estimates of Need and Supply by Specialty

Table 2 reports specialty staffing ratios for seven HMOs in our study, together with GMENAC projections for 1990 for these specialties. In most instances, the GMENAC estimate of both the need and the supply of physicians in 1990 in these specialties far exceeds their utilization in 1983 in the closed-panel, prepaid systems we studied.

In pathology, psychiatry, neurosurgery, family practice, neurology, ophthalmology, orthopedic surgery, anes-

Table 2.—Full-time Equivalent Physicians per 100,000 Population by Specialty: 1983 Data From Seven Large Health Maintenance Organizations and National Projections for 1990 by the GMENAC*

Practice by Specialty	Current Study: 1983 Data From 7 Large Health Maintenance Organizations			GMENAC: 1990	
	FTE Physicians, Mean No.	FTE Physicians, Range	Base No. of Groups	No. of Physicians Needed	No. of Physicians Available
Overall	111.2	98.6-119.7	7	191.4	220.0
Family practice	10.3	2.2-17.5	6	25.2	26.3
Pediatrics	14.9	12.1-21.5	7	15.0	16.1
Internal medicine	28.4	25.9-37.7	7	44.3	52.9
Neurology	1.5	1.2-1.6	6	3.4	3.5
Dermatology	2.3	0.6-2.9	7	2.9	3.0
Psychiatry	3.8	1.9-4.6	7	19.5	14.2
Obstetrics/gynecology	10.7	7.9-12.8	7	9.9	14.1
General surgery	5.8	4.6-7.2	7	9.7	14.5
Neurosurgery	0.6	0.5-1.2	5	1.1	2.1
Ophthalmology	2.9	1.2-3.9	7	4.8	6.7
Orthopedic surgery	3.9	2.9-4.4	7	6.2	8.3
Otolaryngology	2.3	1.0-3.2	7	3.3	3.5
Urology	2.2	0.6-2.4	7	3.2	3.8
Emergency medicine	4.9	0.3-10.0	7	5.5	3.8
Anesthesiology	3.6	1.6-5.0	6	9.1	8.0
Pathology	1.7	0.6-3.1	6	6.5	6.9
Physical medicine	0.8	0.3-1.3	4	1.7	1.0
Radiology	4.4	3.2-5.5	7	8.9	11.4
Administration	1.6	0.8-3.4	7	...	...

*GMENAC indicates Graduate Medical Education and National Advisory Committee; and FTE, full-time equivalent.

thesiology, and radiology (Table 2), and several of the internal medicine specialties (Table 3), the number of physicians projected to be available in 1990 exceeds the utilization of these specialists in the HMOs studied in 1983 by a ratio of more than 2 to 1.

Table 3.—Full-time Equivalent Primary Care and Internal Medicine Specialists per 100,000 Population: 1983 Data From Four Large Prepaid Group Practices* and National Projections for 1990 by GMENAC†

Practice by Specialty	Current Study: 1983 Data From 4 Group Practices			GMENAC: 1990			
	Full-time Equivalent Physicians, Mean No.	%	Base No. of Groups	Physicians Needed, No.	%	Physicians Available, No.	%
Overall	106.0	...	4	191.4	...	220.0	...
Internal medicine							
General internal medicine	23.8	22.4	4	28.8	15.0	30.3	13.8
Allergy	1.1		4	0.8		1.3	
Cardiology	1.6		4	3.2		6.1	
Endocrinology	1.0		4	0.8		1.6	
Gastroenterology	1.5		4	2.7		2.8	
Hematology/oncology	1.6	9.0	4	3.7	8.1	3.4	10.3
Infectious disease	0.6		4	0.9		1.3	
Nephrology	0.6		3	1.1		2.0	
Pulmonary	0.9		3	1.5		2.9	
Rheumatology	0.6		3	0.7		1.2	
Total internal medicine	33.3	31.4	...	44.2	23.1	52.9	24.1
Primary care							
Pediatrics	15.0	14.2	4	15.0	7.8	16.1	7.3
Family practice	5.5	5.2	4	25.2	13.2	25.3	11.5
Obstetrics/gynecology	10.2	9.6	4	9.9	5.2	14.1	6.4
General internal medicine	23.8	22.4	4	28.8	15.0	30.3	13.8
Total primary care	54.5	51.4	...	78.9	41.2	85.8	39.0
Other	51.5	48.5	...	112.6	58.8	134.2	61.0

*Data on primary care and internal medicine specialties were available from only four of the seven group practices included in this study. These four groups had a 1983 combined membership of 529 414 (range, 113 358 to 148 800) and 561 full-time equivalent physicians.

†GMENAC indicates Graduate Medical Education and National Advisory Committee.

Since such specialties as pathology, anesthesiology, and radiology are traditionally hospital based, it is hard

to determine their utilization in a prepaid group practice without comprehensive information on the HMOs' contract arrangements with these specialists for every hospital each specialist uses. In this study, we have tried to capture services provided by such specialties on contract, but because those data were not universally available, our study underestimates the need for these specialists.

To assess how much staffing patterns within large, prepaid group practices may have changed in recent years, we also compared our findings with those of a similar study of six very large, closed-panel HMOs, conducted by Mason⁸ (Table 4). His data support an overall staffing ratio of 99.3 full-time equivalent physicians per 100,000 members compared with the 111.2 physicians per 100,000 members of the current study. This increase is at the rate of 0.87% per year (1970 to 1983).

Comparison of Projections for Primary Care and Internal Medicine Specialists

Table 3 shows our data and the GMENAC projections (both supply and need) for primary care and internal medicine specialties. (Primary care includes pediatrics, family practice, obstetrics/gynecology, and general internal medicine.) For each specialty, our data are from a subset of prepaid plans that provided the most definitive specialty data.

As shown in Table 3, the primary care/specialist balance used by the plans under study is considerably different than the GMENAC recommended (needed) mix.

Examining our specialty data in relation to the GMENAC supply projections, the overall ratio of the GMENAC projected 1990 supply of primary care physicians to our 1983 distribution data is 1.57. Only the distribution of pediatric specialists appears to be in keeping with the GMENAC 1990 supply projections. Obstetrics/gynecology and internal medicine supply-to-utilization ratios are 1.38 and 1.27, respectively. For the internal medicine specialties of cardiology, hematology/oncology, infectious diseases, nephrology, pulmonology, and rheumatology, and also for the specialty of family practice, the projected supply in 1990 exceeds the utilization of physicians in the prepaid health plans we studied in 1983 by more than 2 to 1.

Of the physicians used by the plans under study, 51.4% were primary care physicians. The GMENAC panel recommended a balance of 41.2% primary care physicians to 58.5% other specialists. While the GMENAC panel recommended proportionally fewer general internists, pediatricians, and obstetrician/gynecologists than were actually used by the plans studied, it recommended more than 2.5 times the percentage of family physicians than were actually used in 1983 by the plans in this study.

Table 2 shows significant variance among the plans studied in the number of primary care specialists and emergency physicians that they use, suggesting that the plans have adopted a variety of specialty balances to handle their primary care needs. The most significant

Table 4.—Full-time Equivalent (FTE) Physicians per 100 000 Population by Specialty: 1983 Data From Seven Large Prepaid Group Practices and 1970 Data From Six Large Prepaid Group Practices

Practice by Specialty	Current Study: 1983 Data From 7 Group Practices			Mason*: 1970 Data From 6 Group Practices		
	FTE Physicians, Mean No.	FTE Physicians, Range	Base No. of Groups	FTE Physicians, Mean No.*	FTE Physicians, Range	Base No. of Groups
Overall	111.2	98.6-119.7	7	99.3	83.3-101.7	6
Family practice	10.3	2.2-17.5	6	23.8	11.9-43.5	4
Pediatrics	14.9	12.1-21.5	7	17.1	9.7-22.0	5
Internal medicine	28.4	25.9-37.7	7	27.3	24.3-57.1	2
Neurology	1.5	1.2-1.6	6	0.9	0.8-1.1	4
Dermatology	2.3	0.6-2.9	7	2.2	1.0-3.0	4
Psychiatry	3.8	1.9-4.6	7	1.9	0.7-2.1	3
Obstetrics/gynecology	10.7	7.9-12.8	7	10.3	6.9-11.1	6
General surgery	5.8	4.6-7.2	7	8.1	5.6-12.4	6
Neurosurgery	0.6	0.5-1.2	5	0.9	0.7-1.8	3
Ophthalmology	2.9	1.2-3.9	7	2.8	2.1-3.1	5
Orthopedic surgery	3.9	2.9-4.4	7	3.8	2.9-4.0	5
Otolaryngology	2.3	1.0-3.2	7	2.2	2.0-2.6	5
Urology	2.2	0.6-2.4	7	1.6	1.0-2.2	5
Emergency medicine	4.9	0.3-10.0	7	...	...	...
Anesthesiology	3.6	1.6-5.0	6	2.3	1.1-3.3	4
Pathology	1.7	0.6-3.1	6	1.3	0.7-2.1	5
Physical medicine	0.8	0.3-1.3	4	1.0	0.8-1.1	2
Radiology	4.4	3.2-5.5	7	3.4	2.1-4.0	6
Administration	1.6	0.8-3.4	7	...	...	...

*Mean number of physicians per 100000 members belonging to the noted base number of groups.

variance is in the use of family physicians, ranging from a low of 2.2 family physicians per 100,000 plan members to a high of 17.5. As would be expected, the plans with fewer family physicians had more general internists, obstetrician/gynecologists, and pediatricians.

Both the wide range of variability in the use of family physicians in the plans studied and the significant difference between the actual number used and the number projected by the GMENAC for 1990 invite a closer look. Comparing the number of family physicians used in the six plans for which we have specialty data (293.18) with the total number of physicians in those plans (4533.52), we found that family physicians represented 6.47% of the physicians used by those plans. Data from the American Medical Association's 1983 publication *Physician Characteristics and Distribution in the United States*⁶ show that family physicians represent 6.9% of all physicians (35,952/519,546). The use rate of family physicians for the plans studied was therefore quite close to their actual representation for that year among all physicians.

Comment

Physician utilization in closed-panel, prepaid systems is not a satisfactory basis for projecting the utilization of physicians by the entire population of the United States. However, we might expect that given cost-containment concerns, the future utilization of physicians might more closely approach that of prepaid, closed-panel health care systems on one end of the continuum of physician projections than the more access-oriented modified need system envisioned by the GMENAC on the other. Two major conclusions emerge from our analysis: (1) the physician surplus under a limited-resources scenario will

be even larger than that projected by the GMENAC, and (2) the need for primary care and generalist physicians will exceed the supply.

The first conclusion (that the physician surplus is likely to be larger than the GMENAC projection) is not particularly surprising. Tarlov,⁷ in his revised estimate of physician supply for 1990 and the year 2000, noted that there will be a large discrepancy in physician need between prepaid group practices and the remaining non-federal and federal practice sectors.

Schwartz et al⁹ recently have attempted to demonstrate that there will be no surplus of physicians up to the year 2000 unless "cost containment efforts lead to considerable rationing of beneficial services." At this time, every indication suggests a real concern by government and industry over the sustained rate of increase of health care costs in the United States. This is leading to an ever-expanding drive toward cost-containment and, in some quarters, the call for some type of government-regulated national health service. The utilization of physicians in such a system is unknown, but, a safe prediction might be that physician utilization in closed-panel HMO settings may be used as a standard of measure either by government, by industry, or by third-party payers.

The specialty balance findings are perhaps less intuitive. The HMOs we studied used more primary care and internal medicine specialists than would be predicted by the GMENAC, and significantly fewer other specialists. In the plans we studied, 51.4% of the physicians were primary care physicians vs the 41.2% recommended by the GMENAC. Family physicians were used by the

plans studied in proportion to their availability at the time, but at a rate substantially below the GMENAC projected need for family physicians (5.2 vs 13.2 family physicians per 100,000).

The GMENAC panel projected that both the number of family physicians trained and needed would increase significantly by 1990. However, a study reported in 1986 by Ricketts et al¹⁰ concludes that the GMENAC supply and need targets are unlikely to be met. They note that the number of physicians entering their first postgraduate year of training in family practice appears to have leveled off substantially below the GMENAC estimates, with fill rates for residency positions hovering at slightly less than 80%. With declining resources for family practice training programs, Ricketts et al conclude that it would not be reasonable to expect either the residency fill rate or the number of residencies available to increase.

On the assumption that the number of family physicians will not increase to the GMENAC-predicted levels, other primary care specialties (eg, internal medicine) might be expected to increase to fill the balance. However, in 1987, Kletke et al¹¹ noted that despite an expected increase of 121% in the number of internists between 1978 and 1998, subspecialists will account for the bulk of the increase. They project that the number of subspecialists will increase 206% while general internists will increase 77%. While changes in demography and morbidity will affect demand, they note the unlikelihood of a threefold increase in subspecialty demand. They further note that nearly one fifth of the general internists entering practice will have had one year of subspecialty training and will probably refer patients to subspecialists less often. They conclude that by 1998 it is likely that the practices of some subspecialties will primarily consist of general internal medicine.

Recently, Steinwachs et al¹² also reported the requirements for primary care physicians in three HMOs and compared them with the GMENAC-based requirements for primary care physicians in 1990. The three HMOs represented three different HMO models (a staff model, a group practice model, and an independent practice association model); the closed-panel model was not included. The investigators adapted a GMENAC methodology to determine physician requirements on the basis of the experience of the three HMOs. After adjusting their data for patients greater than 65 years of age, for the number of patients below the poverty level, and for the out-of-plan services used by the HMOs (corrective factor of 1.25), they found that 20% fewer primary care physicians for children and 50% fewer primary care physicians for adults would be needed in 1990 compared with GMENAC projections.

We could not derive similar data for general pediatrics since we were unable to segregate pediatric specialists from general pediatricians. However, using our data for

general internal medicine and family practice physicians (and without adjusting for age, out-of-plan care, and enrollees below the poverty level), our study demonstrated the demand for 46% fewer adult health care physicians (family physicians and general internists) than was projected by the GMENAC for 1990. This is similar to the adjusted value of 50% fewer physicians in the same categories projected by Steinwachs et al.¹² If our data are adjusted using Steinwachs and coworkers' corrective factor of 1.25, there would be 32% fewer physicians needed in 1990 compared with GMENAC projections.

In addition to the way in which care systems are structured, other changing circumstances may also have a profound effect on the need for physicians. These may include changes in morbidity and mortality, technological advances, the aging of the population, use of allied health practitioners, and changes in physician life-styles. The present study does not take these and other unpredictable factors into account.

We conclude there is little difference in physician-to-member ratios between Mason's study⁸ (99.3/100,000) and ours (111.2/100,000). The results may not be directly comparable due to several methodological differences. Unlike our study, Mason's does not include "other" categories, contract physicians, or administrative physicians. These omissions decrease the ratio of physicians to members and underrepresent the number of physicians actually involved in the care of the plan enrollees. For this reason, the small differences between our findings and those of Mason may represent little genuine change between 1970 and 1983. This suggests that staffing patterns in the very large, closed-panel HMOs have remained relatively stable during a period of rapid change in the health care system.

Others, however, have used changes in physician staffing in closed-panel HMOs over time to help estimate physician need in future years.⁹ Assuming that the 0.87% yearly rate of increase during the years 1970 to 1983, the time between Mason's study and this study, is real, the projected ratio of physicians to members in the year 2000 would be approximately 129/100,000 compared with the physician supply projections of 233/100,000. However, by documenting the mix of specialists within very large, relatively closed, prepaid systems, our estimate of 111 physicians per 100,000 population, based on 1983 data, lies on one end of a continuum of possible projections of physician need.

Our data further suggest that in an extensive system that attempts to manage health care resources, primary care physicians will be in higher demand than was estimated by the GMENAC. This level of utilization of physician resources by specialty would have a profound effect on the production, training, specialization, and distribution of physicians by the turn of the century.

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Drugs For Epilepsy

THE MEDICAL LETTER

TREATMENT of epilepsy should begin with a single drug, increasing the dosage gradually until seizures are controlled or adverse effects become intolerable. If seizures continue and further increases in dosage appear inadvisable because of adverse effects or high serum

concentrations of the drug, at least one and sometimes a second alternative drug should be tried before considering use of two drugs at the same time. The drugs of choice and alternative drugs for treatment of the most common types of epileptic seizures are listed below.

TREATMENT OF SEIZURES

Seizure Disorder	Drugs	Usual Daily Dosage		Usual Therapeutic Serum Concentrations
		Adults	Children	
PRIMARY GENERALIZED TONIC-CLONIC (<i>GRAND MAL</i>)				
Drugs of Choice:	Carbamazepine	600-1200 mg	20-30 mg/kg	6-12 µg/ml
	or Phenytoin	300-400 mg	4-7 mg/kg	10-20 µg/ml
	or Valproate ¹	1000-3000 mg	15-60 mg/kg	50-100 µg/ml
	Alternatives: Phenobarbital	120-250 mg	3-5 mg/kg	15-35 µg/ml
	Primidone	750-1500 mg	10-25 mg/kg	6-12 µg/ml
PARTIAL, INCLUDING SECONDARILY GENERALIZED				
Drugs of Choice:	Carbamazepine	600-1200 mg	20-30 mg/kg	6-12 µg/ml
	or Phenytoin	300-400 mg	4-7 mg/kg	10-20 µg/ml
Alternatives:	Phenobarbital	120-250 mg	3-5 mg/kg	15-35 µg/ml
	Primidone	750-1500 mg	10-25 mg/kg	6-12 µg/ml
ABSENCE (<i>PETIT MAL</i>)				
Drugs of Choice:	Ethosuximide	750-2000 mg	20-40 mg/kg	40-100 µg/ml
	or Valproate ²	1000-3000 mg	15-60 mg/kg	50-100 µg/ml
Alternative:	Clonazepam	1.5-20 mg	0.01-0.2 mg/kg	.013-.072 µg/ml
ATYPICAL ABSENCE, MYOCLONIC, ATONIC				
Drug of Choice:	Valproate ¹	1000-3000 mg	15-60 mg/kg	50-100 µg/ml
Alternative:	Clonazepam	1.5-20 mg	0.01-0.2 mg/kg	.013-.072 µg/ml

STATUS EPILEPTICUS

Drug of Choice		Usual Initial Dose	Usual Rate	Repeat Doses PRN	Maximum /24 Hrs.
Diazepam, IV	Adults	5-10 mg	1-2 mg/min ³	5-10 mg q20-30 min	100 mg
	Children	0.25-0.4 mg/kg ⁴	(See footnote 3)	0.25-0.4 mg/kg ⁴ q20-30 min	40 mg
Phenytoin, IV	Adults	15-20 mg/kg	30-50 mg/min	100-150 mg q30 min	1.5 grams
	Children	15-20 mg/kg	0.5-1.5 mg/kg/min	1.5 mg/kg q30 min	20 mg/kg
Phenobarbital, IV	Adults	10-20 mg/kg	25-50 mg/min	120-240 mg q20 min	1-2 grams
	Children	20 mg/kg	25-50 mg/min	6 mg/kg q20 min	40 mg/kg

- 1. Not FDA-approved unless absence is involved
- 2. First choice if primary generalized tonic-clonic also present
- 3. Slower rates of administration should be used for children
- 4. To a maximum of 5-10 mg

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CARBAMAZEPINE — Carbamazepine (*Tegretol*; and others) is recommended for treatment of generalized tonic-clonic seizures and for partial seizures. Intolerance to the drug can often be avoided by starting with 200 mg bid and increasing the dosage at weekly intervals in increments of 200 mg per day, up to the usual mainte-

nance dosage of 600 to 1200 mg per day (divided into three or four doses). Monitoring serum concentrations of carbamazepine alone may be misleading, since an active metabolite, carbamazepine-10,11 epoxide, may also cause toxic effects (PN Patsalos et al, *Lancet*, 2:496, 1985).

Carbamazepine can cause drowsiness, blurred vision, transient diplopia and ataxia, but it probably has less effect on cognitive function than phenytoin. Hematological toxicity is rare, but can be serious; agranulocytosis and aplastic anemia can occur. Stevens-Johnson syndrome, cardiac toxicity, hypo-osmolality due to an anti-diuretic effect and hepatitis, which is sometimes fatal, have been reported. Carbamazepine is carcinogenic and teratogenic in rats; whether it is teratogenic in humans remains to be established.

Therapeutic failure associated with poor bioavailability has been reported with both generic carbamazepine and *Tegretol* tablets (G Koch and JP Allen, *Arch Neurol*, 44:578, 1987; JT Gilman et al, *Pediatrics*, 82:518, Sept 1988).

PHENYTOIN (diphenylhydantoin) — Phenytoin (*Dilantin*; and others) is also effective for treatment of generalized tonic-clonic seizures and for partial seizures. It is available for both oral and parenteral use. An oral suspension is available, but inadequate mixing of the suspension may lead to erroneous doses. Different oral formulations of phenytoin may not be equivalent (*Medical Letter*, 22:49, 1980).

Phenytoin causes many adverse effects. It may interfere with cognitive function in learning situations. Nystagmus may occur with therapeutic serum concentrations, and is nearly always present at higher concentrations; it may be less frequent in children. At serum concentrations higher than 30 $\mu\text{g/ml}$, drowsiness, ataxia and diplopia often occur. Gingival hyperplasia, coarsening of facial features and hirsutism can be serious problems in some patients. A morbilliform rash may occur, usually in the first 10 days of treatment, and rarely progresses to exfoliative dermatitis or the Stevens-Johnson syndrome; the drug should be stopped immediately if a rash appears.

Other adverse effects include a lupus-like syndrome, hepatic granulomas, hepatitis leading rarely to fatal hepatic necrosis, lymphadenopathy, pseudolymphoma, nephritis, megaloblastic anemia, acute pulmonary infiltrates, peripheral neuropathy, and rickets and osteomalacia due to interference with vitamin D metabolism. Serum folic acid and vitamin K concentrations may be depressed, and bleeding disorders have been reported in infants born to mothers taking phenytoin. Congenital abnormalities, including mental deficiency, have occurred in children whose mothers took the drug during pregnancy (DC Van Dyke et al, *J Pediatr*, 113:301, 1988).

VALPROATE — Valproate (*Depakene*; *Depakote*; and others) is currently approved by the US Food and Drug Administration (FDA) for marketing only for treatment of absence seizures but, because it is effective and usually well tolerated, it is also widely used for many other types of seizures, including primary generalized

tonic-clonic, myoclonic and atonic seizures, and for patients with mixed forms of generalized seizures (JK Penry ed, *AM J Med*, 84 suppl 1A, 1988). A recent report indicates the drug may also be useful for treatment of partial seizures (JC Dean and JK Penry, *Epilepsia*, 29:140, 1988).

Drowsiness due to valproate alone is usually slight and temporary, and cognitive effects are minimal. Serious adverse effects of the drug are uncommon, but fatal liver failure has occurred rarely, particularly in children less than two years old taking valproate in addition to another anticonvulsant (FE Dreifuss et al, *Neurology*, 37:379, 1987). A higher incidence of fatal liver failure has been reported in West Germany, including cases in older children taking valproate alone (D Scheffner et al, *Epilepsia*, 29:530, 1988). Chronic liver disease can also occur. Even in the absence of hepatic dysfunction, valproate can interfere with conversion of ammonia to urea and infrequently causes lethargy associated with increased blood ammonia concentrations (MJ Eadie et al, *Med Toxicol*, 3:85, 1988). Pancreatitis can also occur, and interstitial nephritis has been reported (C-Y Lin and H Chiang, *Nephron*, 48:43, 1988).

More common adverse effects include nausea and vomiting, which may be minimized by using the enteric-coated formulation (*Depakote*) or by taking the drug with food. Weight gain, hair loss, rash, tremor, headache, insomnia, leukopenia, red blood cell aplasia and thrombocytopenia have been reported. Neural tube defects and other congenital malformations have developed in infants born to women who took valproate during pregnancy.

PHENOBARBITAL — Phenobarbital continues to be widely used for treatment of generalized tonic-clonic seizures and partial seizures. Its half-life is about 100 hours, and steady-state serum concentrations may not be reached for several weeks. Ease of absorption has made phenobarbital the drug of choice for seizures in infants, but effects on cognitive function have led to decreased use for older children and adults. Sedation and behavior disturbances including hyperactivity, loss of concentration and depression are the principal adverse effects (DA Brent et al, *Pediatrics*, 80:909, 1987). As with phenytoin and primidone, hemorrhage can occur in infants born to mothers treated with phenobarbital.

PRIMIDONE — Primidone (*Mysoline* and others) is effective for the same types of seizures as phenobarbital. The anticonvulsant effect is due both to the drug itself and its metabolites, which include phenobarbital; when monitoring is necessary, both primidone and phenobarbital concentrations should be measured. Sedation, vertigo, nausea and ataxia occur frequently unless the drug is started in very low dosage, such as 50 to 100 mg daily, with gradual increases to two- to three-day intervals. Primidone can also cause disturbances in behavior, difficulty in concentration and loss of libido.

ETHOSUXIMIDE — Ethosuximide (*Zarontin*) is recommended for treatment of uncomplicated absence seizures. Adverse effects include nausea, vomiting, leth-

argy, hiccups and headache; eosinophilia and occasionally leukopenia may occur. Erythema multiforme, Stevens-Johnson syndrome and a lupus-like syndrome have been reported rarely. Dose-related psychotic behavior can occur with toxic serum concentrations of ethosuximide.

CLONAZEPAM — Clonazepam (*Klonopin*; formerly *Clonopin*) is used to treat myoclonic, atonic and absence seizures that may be resistant to treatment with other anticonvulsants. It is generally less effective for absence seizures than ethosuximide or valproate, and tolerance to its effects may develop. Adverse effects of clonazepam include drowsiness, ataxia and behavior disorders.

TREATMENT OF STATUS EPILEPTICUS — All drugs used to treat status epilepticus can be lethal if given too rapidly or in overdosage. Intravenous diazepam (*Valium*; and others) can be given first; lorazepam (*Ativan*) is comparable in effectiveness and may act longer,

although its onset of action is not as rapid. Either should be administered with caution to patients who have received barbiturates; concomitant use of IV benzodiazepines and barbiturates increases the risk of respiratory depression and apnea. The anticonvulsant effect of diazepam is short-lived, and it should be followed immediately by an intravenous loading dose of phenytoin to avoid recurrence of seizures. Some clinicians prefer IV phenytoin over diazepam as the first drug for treatment of status, especially for patients maintained on phenytoin. Phenytoin does not act as promptly as diazepam, but its effects last longer. Other clinicians prefer to use IV phenobarbital (DM Shaner et al, *Neurology*, 38:202, 1988).

INTERACTIONS — All of these drugs are notable for their interactions with each other and with other drugs. Some of their interactions with each other are listed below. For interactions of antiepileptics with other drugs, see *The Medical Letter Handbook of Adverse Drug Interactions*, 1989.

SOME ANTIEPILEPTIC DRUG INTERACTIONS

Interacting Drugs	Adverse Effects (Probable Mechanism)	Comments and Recommendations
Carbamazepine, with:		
Phenobarbital	Difficulty in evaluating carbamazepine concentration (increased metabolism to the epoxide)	Low or normal carbamazepine concentration may not be significant if epoxide is increased
Phenytoin	Decreased carbamazepine effect (increased metabolism) Altered phenytoin effect (mechanism not established)	Monitor carbamazepine and phenytoin concentrations; both increased and decreased phenytoin concentrations have been reported
Primidone	Decreased primidone effect and increased phenobarbital effect (increased conversion of primidone to phenobarbital) Decreased carbamazepine effect (decreased metabolism)	Monitor primidone and phenobarbital concentrations Monitor carbamazepine and carbamazepine epoxide concentrations
Valproate	Decreased valproate effect (increased metabolism)	Monitor valproate concentration
Phenobarbital, with:		
Clonazepam	Decreased clonazepam effect (increased metabolism)	Monitor clonazepam concentration
Valproate	Increased phenobarbital toxicity (decreased metabolism)	Monitor phenobarbital concentration
Phenytoin, with:		
Carbamazepine	Decreased carbamazepine effect (increased metabolism) Altered phenytoin effect (mechanism not established)	Monitor carbamazepine and phenytoin concentrations; both increased and decreased phenytoin concentrations have been reported
Clonazepam	Decreased clonazepam effect (increased metabolism) Variable effect on phenytoin concentration (mechanism not established)	Monitor clonazepam and phenytoin concentrations
Primidone	Decreased primidone effect and increased phenobarbital effect (increased conversion of primidone to phenobarbital)	Monitor primidone and phenobarbital concentrations
Valproate	Increased phenytoin toxicity (displacement from binding)	Conflicting reports; monitor phenytoin concentration and clinical status
Valproate, with:		
Carbamazepine	Decreased valproate effect (increased metabolism)	Monitor valproate concentration
Clonazepam	Clonazepam may precipitate absence status (mechanism not established)	Avoid concurrent use
Diazepam	Possible IV diazepam toxicity (displacement from binding and decreased metabolism)	Use IV diazepam with caution
Ethosuximide	Possible ethosuximide toxicity (decreased metabolism)	Highly variable; clinical significance not established; monitor ethosuximide concentration
Phenobarbital	Increased phenobarbital toxicity (decreased metabolism)	Monitor phenobarbital concentration
Phenytoin	Increased phenytoin toxicity (displacement from binding)	Conflicting reports; monitor phenytoin concentration and clinical status

Insect Repellents

INSECT repellents have been used on the skin for many years, primarily to prevent mosquito bites. With recent increased concern about Lyme disease, skin and clothing repellents are now also recommended for protection against ticks.

SKIN REPELLENTS — Currently available insect repellents for application to the skin (*Off!*; and others) are usually effective for one to several hours, but can be removed by absorption, evaporation, rain, sweating, swimming or wiping, and must be reapplied to maintain effectiveness. The most effective topical insect repellent known is N,N-diethyl-m-toluamid, commonly called "deet." Deet repels a variety of mosquitoes, chiggers, ticks, fleas and biting flies; no topical repellent is effective against stinging insects, such as bees and wasps. The US Armed Forces have long used 75% deet in ethanol, but several products that equal or exceed this concentration are now available commercially. A new long-acting deet formulation, which is expected to be available to the Armed Forces this summer and commercially available next year, contains 35% deet with an added polymer; the polymer apparently prevents loss of deet from the skin surface through absorption and evaporation.

Other repellents effective against both mosquitoes and ticks, but less so than deet, include 2-ethyl-1,3-hexanediol (Rutgers 612) and dimethyl phthalate. Citronella-based repellents (*Natrapel*; and others) may provide short-term protection against mosquitoes, but are probably not effective against ticks.

A CLOTHING REPELLENT — Permethrin, actually a pesticide rather than a repellent is used for treatment of lice (*Nix - Medical Letter*, 28:89, 1986) and is also marketed as a clothing spray for protection against both mosquitoes and ticks. The aerosol is available in many areas of the USA as *Permanone Tick Repellent*, sold mostly in lawn and garden stores or sports stores. Manufactured by Fairfield American in Newark, NJ and distributed by Coulston International, Easton, PA, it is non-staining, nearly odorless and resistant to degradation by light, heat or immersion in water.

CLINICAL TRIALS — Mosquitoes - A field trial conducted with US Air Force volunteers in an area of Alaska with a large population of mosquitoes, but few mosquito-borne diseases, tested both the new 35% long-acting cream formulation of deet applied to exposed skin and permethrin treatment of clothing. The deet formulation provided greater than 99% protection for more than eight hours (a mean of four mosquito bites per person per hour), while a permethrin-treated uniform (0.125 mg/cm²) alone provided 93% protection (78 mosquito bites/hour), compared to 1,188 bites per hour with no protection; using both deet on skin and permethrin on clothing provided 99.9% protection (one bite/hour) (TH Lillie et al, *J Med Entomol*, 25:475, 1988). Another trial conducted in Pakistan eight hours after application of the same long-acting deet formulation found that the combination of deet and permethrin-treated clothing provided 100% protection from mosquito bites; long-acting deet repellent alone gave 89% protection (a mean of 3.9 bites), compared to 57% (14.8 bites) with treated clothing alone and 34.4 bites with no repellent (LL Sholdt et al, *J Am Mosq Control Assoc*, 4:233, 1988).

An earlier field trial in Australia had found two long-

acting repellents (*3M Insect Repellent Lotion*, 33% deet; *Biotek Long-Acting Insect Repellent*, 42% deet) no more effective (56% and 61% protection over 14 hours) than the standard military formulation of 75% deet (54% protection) in preventing bites. Any one of the three used together with permethrin-treated clothing provided the most protection (75%, 82% and 80%) (RK Gupta et al, *J Am Mosq Control Assoc*, 3:556, 1987).

Ticks — A pressurized spray of 0.5% permethrin was compared with 20% and 30% concentrations of deet for use on military field uniforms in an area of Cape Cod infested with *Ixodes dammini*, the principal vector of Lyme disease (and babesiosis) in the northeastern USA. A one-minute application of permethrin provided 100% protection, compared to 86% and 92% protection with one-minute applications of 20% and 30% deet (CE Schreck et al, *J Med Entomol*, 23:396, 1986). Permethrin-treated clothing has also been effective against ticks found in California (RS Lane and JR Anderson, *J Med Entomol*, 21:692, 1984).

SKIN-SO-SOFT — A commercial concentrated bath oil, *Avon Skin-So-Soft*, has come into wide use as a "folk medicine" mosquito repellent. This product contains diisopropyl adipate, mineral oil, isopropyl palmitate, dioctyl sodium sulfosuccinate, fragrance, and the sunscreen benzophenone-11. In one study, the bath oil did repel *Ae. aegypti*, the mosquito carrier of yellow fever (LC Rutledge et al, *Mosquito News*, 42:557, 1982) but, according to Medical Letter consultants, *Skin-So-Soft* may protect against mosquitoes for as little as 10 to 30 minutes, and the safety of repeated, widespread application of the concentrated bath oil to the skin is unknown.

ADVERSE EFFECTS — Deet is absorbed through the skin into the systemic circulation; about 10% to 15% of each dose can be recovered from the urine. Toxic and allergic reactions have been reported. The drug has been associated with bullous eruptions in the antecubital fossa and contact urticaria, and toxic encephalopathy has occurred with excessive or prolonged use, particularly in infants and children (DL Edwards and CE Johnson, *Clin Pharm*, 6:496, 1987). With the higher concentrations now available, brief exposure to smaller amounts has caused serious reactions in children and adults, including anaphylaxis and grand mal seizures (JD Miller, *N Engl J Med*, 307:1341, 1982; EH Roland et al, *Can Med Assoc J*, 132:155, 1985). Ingestion of deet can be fatal; two of five patients aged one to 33 years died following coma, seizures, and hypotension that occurred within one hour after ingestion (M Tenenbein, *JAMA* 258:1509, 1987).

Permethrin is toxic to the nervous system of insects but, in mammals, the drug is poorly absorbed and then rapidly inactivated by ester hydrolysis. Objective signs of skin toxicity such as edema, erythema and rash have been uncommon, and adverse system effects have not been reported.

CONCLUSION — Deet-containing insect repellents applied to the skin or clothing can help prevent mosquito and tick bites, but deet may cause allergic and toxic effects in children and adults, especially when used on the skin repeatedly in high concentrations. Wearing protective clothing treated with permethrin in addition to using deet on exposed skin provides the greatest degree of protection against mosquito and tick bites.

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CONNECTICUT MEDICINE, MAY 1989

View from the Hill

JAMES E. BRYAN

AFTER more than six months of negotiation, the American Medical Association has yielded to a dictate by the Federal Trade Commission to finally abandon the profession's time-honored view that advertising by physicians is inherently unethical.

In 1982, the AMA Council on Ethical and Judicial Affairs yielded to a federal appellate court ruling that affirmed an FTC order declaring any advertising ethical, providing only that it not be found fraudulent or deceptive. However, the AMA council, seemingly anxious to retain as much as it could of the traditional total stricture, inserted qualifying language in its 1982 interpretive opinion to which the FTC took exception. The FTC claimed that the council had diluted the commission's intent not only to legalize, but to encourage every form and manner of competitive advertising. Only thus, the FTC held, could the practice of medicine be effectively commercialized in keeping with the Administration's theory that all-out price competition alone could bridle the continuing inflation of medical care charges.

Thus, the FTC Docket 9064 prohibits medical societies or other authorities from ruling unethical or objectionable any advertising by a physician unless it is found false or deceptive. Physicians are specifically freed to publicize themselves through any form of public or private communication, including newspapers, magazines, telephone directories, radio, television or direct mail. There are said to be some (one hopes not many) who will fully avail themselves of these privileges.

The Washington Post has a weekly "Health Section" featuring interesting articles on a variety of medical topics. Besides the usual advertisements for department store opticians, weight-control emporia and podiatry, services are advertised for treatment of panic or anxieties; "diseases of affluence"; geriatric care featuring cardiovascular studies; acupuncture; care of diabetic foot problems; aesthetic facial surgery; travel immunization; home nursing; AIDS; etc.

Indeed, legal authorization, political encouragement and popular acceptance (is any commercial practice verboten today?) all portend a growing volume of advertising by physicians and other entities in the field. This kind of aggressive marketing not only feeds on itself, it tends to proliferate and multiply specialties, loosening or fracturing the bonds between people and their personal primary care or family physicians. Public advertising tends to diminish physicians as professionals and to demean medicine as a noble and widely revered profession.

JAMES E. BRYAN, Washington Correspondent, *American Family Physician*.

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Perhaps most regrettable, commercial advertising of medical services tends to favor self-promoters. In that context, the council gently raised the key issue of "whether advertising or publicity, regardless of format or content, is true and not materially misleading." Physicians are reported to be at liberty to include information about their educational backgrounds, the basis on which they set their fees, their charges for specified services, and the credit or other methods of payment offered their patients. Patient testimonials are discouraged, as are quality claims—as one hopes they would be.

Kirk Johnson, AMA general counsel, said the AMA negotiated the new, more broadly permissive statement—inhibiting only statements or claims clearly fraudulent or deceptive—without important compromise. "We made a few changes and kept the heart of the opinion," he said. "That's the deal we made." Indeed, counsel "negotiated" under a threat that if the AMA had not accepted the FTC's terms, the commission would have required the AMA to withdraw its entire 1982 statement, making the FTC act the sole rule governing physician advertising. In that event, Counsel Johnson declared, "We would have been left in the same boat [as those advertising] cereal or vacuum cleaners."

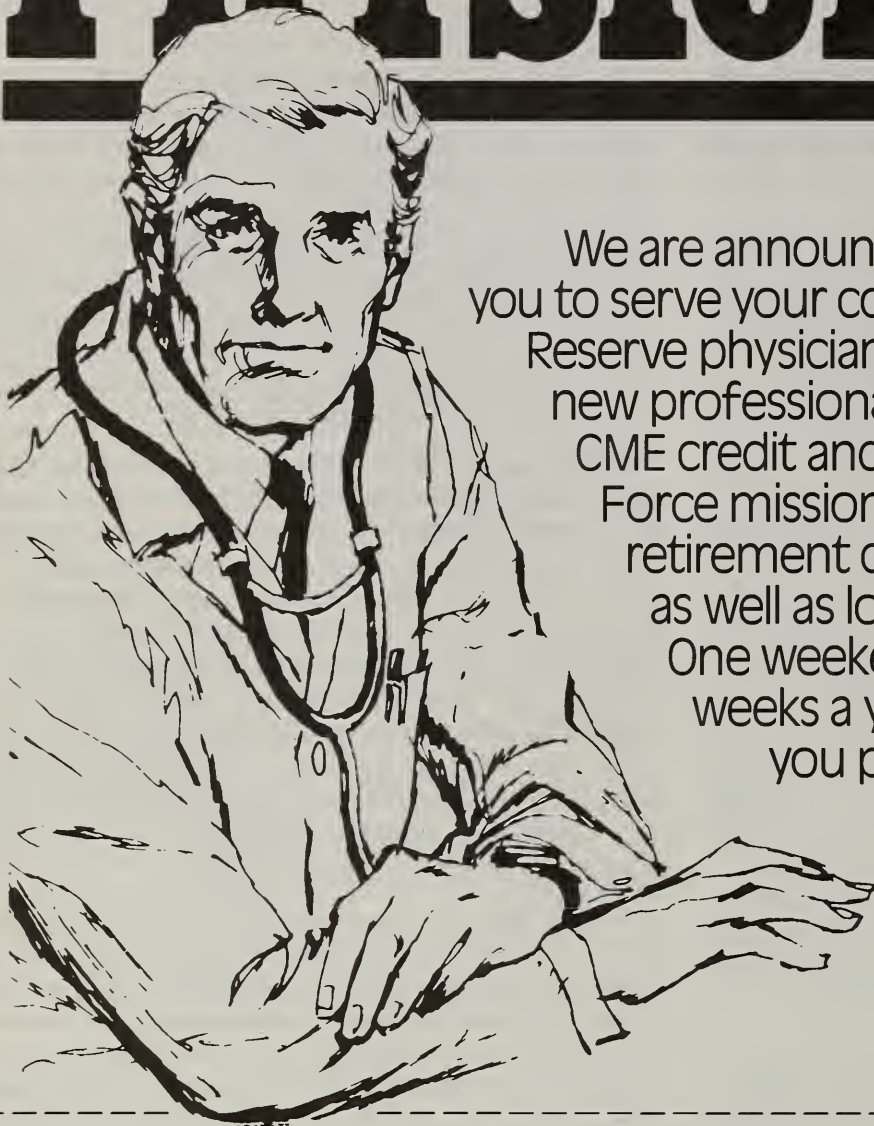
The FTC appears to be offering medicine a seat in that boat. Terry Winslow, deputy director of the FTC's Bureau of Competition, acknowledged that advertising for personal services differs to some extent from advertising for products, and "advertising for services that are complex is to some extent different from advertising things that are entirely routine," signaling a new depth of philosophic discrimination.

But, Winslow explained, the reason complex, personal services "are different is that it might be [easier] for consumers to be deceived about something that is very complicated, such as services of the type that physicians provide. The ultimate standard, however, I think, is the same for physician advertising as for other advertising—is it likely to deceive consumers?"

The argument is circular. But a wound has been inflicted on the profession by an administration dedicated to an ideologic notion that it can serve the public well-being by persuading a profession dedicated to a crucial human service to abandon humanity's oldest code of ethics for that of a second-hand car dealer.

In summary, the AMA counsel is quoted as assuring the client that "we came out very well. We convinced them [the FTC] that medical care is highly susceptible to fraudulent advertising." A few more triumphs like that, and only born scalawags and those with street smarts will apply for enrollment in American medical schools.

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Semantics As Substance: Life Support Systems or Medically Invasive Technology?

Most physicians are aware of how the technological advances of the last quarter century have complicated the ethics of health care delivery. We all struggle to make appropriate decisions about what technologies we should use and to what purpose we should use them. I wonder how often we recognize how our use of language actually shapes our thoughts and complicates our decisions in these and other matters.

The careful choice of language helps us to manage our perceptions. Professor Edward Higgins, the English semanticist of George Bernard Shaw's *Pygmalion*, understood this power; he succeeded in metamorphosing a "common guttersnipe" into a "consort for royalty" by teaching her the language of the upper classes. More recently, Larry Speakes, President Reagan's former press secretary, used language as a strategy to define public perceptions by claiming that certain statements were "disinformation" rather than dishonest.

Physicians seem to be capricious with their use of language. For example, I believe that we confuse ourselves and our patients when we speak of "withdrawing life support" from patients who require invasive care. Webster acknowledges that support includes the act of upholding by "aid, encouragement, or countenance." Patients with potentially fatal diseases, and their loved ones, require much emotional support. The decision not to utilize certain technologies in caring for a patient does not constitute the withdrawal of that support. A physician who, in consultation with a patient (and/or patient's family), ceases to utilize medically invasive technology is still providing medical care and support at a level consonant with his or her own judgment and the patient's interests. The concept of "withdrawing life support" infuses an emotional charge which interferes with the ability to make clear judgments; it can confuse physicians, patients, and policy makers, alike.

Physicians often seem ill at ease when discussing medical practice issues with the general public. I suggest that we are uncomfortable using terms that have been defined by people not familiar with patient care. For example, Barnhart's dictionaries cite the use of the term "life sup-

port system" in reference to oceanography five years before the use of "life support" in a medical context. Every borrowed term will bring to its new use its old connotations; they can shape how we think in ways of which we are not aware. "Life support" may be appropriate for the engineer designing underwater habitats but is deceptive and misleading when applied to patient care.

Current medical technology is in many ways miraculous. However, the same tools which help us to restore health to critically ill patients can be used to support so-called "vital" functions in patients for whom hope for a meaningful recovery has passed. We have the means to place a tube in the trachea, connect it to a ventilator, and maintain respirations indefinitely in patients whom we know will never breathe again. We can utilize the wonders of the Swann-Ganz catheter to deliver powerful pharmaceuticals directly into the heart and to monitor their effects, even after our patient's brain has forever ceased to think. We can provide nutrition for patients who will never even be aware that they have stopped eating. In these instances, our powerful interventions are not performing any health restoring function. We should not presume to label these activities "life support." "Medically invasive technologies" is more descriptive, more accurate, and, I believe it is a more appropriate term for us to use.

Each physician needs to make an affirmative decision as to what type of support is most appropriate for any given patient. We should discuss with our patients and their families our judgment as to which technologies are appropriate to use and exactly what each intervention can hope to accomplish. If we avoid the use of emotionally charged terminology, we will liberate our patients from the need to face the artificial burden the language would impose. We are not wise enough to be able to state with certainty the outcomes of our medical choices; Karen Ann Quinlan remained in her vegetative state long after her "life support systems" were discontinued. We must acknowledge the distinction between the process, or technology, and the purpose of patient care. Our language needs to reflect this difference; we also need to advocate the use of appropriate terms in the lay press and in our journals. This will improve the ability of physicians and patients alike to make rational decisions regarding the use of technology. Decisions regarding medical ethics are sufficiently complex without further confusing the issues through the use of inexact or misleading language.

Most professions have a private technical language, or

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jargon; medicine is no exception. Medical jargon is further complicated by our attempts to contract the jargon when we describe things familiar to us. I am concerned that at times we may carelessly substitute these contractions when we discuss the more complicated thought processes involved in patient care. We may project an image of physicians as sloppy thinkers. Jargon can produce its own subtle conditioning—reinforcing the substitution of the jargon's literal meaning at the expense of the concept it was meant to describe. Further, when our jargon is picked up by the lay press or our patients it is often interpreted literally; the metaphor or abbreviation becomes the message. This should not be surprising as it often requires a medical background to be able to fill in the subtleties of meaning which our contracted language has ignored. As lay opinions may have significant influence on those who create health care policy, it is easy to see how our careless use of language can have broad and unhappy consequences on the practice of medicine.

Physicians continue to be society's health care experts. We must hold ourselves to the highest standards. Language is the vehicle by which we define concepts; it shapes attitudes. We must use the power which proper language offers. We should choose our words with care and accuracy and then reinforce our word choices by actively challenging the use of inappropriate terminology by the general public, the government, and our colleagues. Otherwise, we risk losing our position of leadership in health policy, unable to articulate our real concerns in a complex and rapidly changing world.

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Animals in Research

Within this century, spectacular advances have been made in the prevention, diagnosis, and treatment of many diseases. With expansion of our basic knowledge of processes involving biochemistry, physiology, and molecular biology, important new directions in medicine have been taken. Although medicine requires research for the development of new thought, the research process itself is less well understood.

Since the late 1800s, the American Medical Association has consistently supported the humane use of animals for biomedical research. Research involving animals is essential to improving the health and well-being of the American people, and the American Medical Association actively opposes any legislation, regulation, or social action that inappropriately limits such research. Most

Americans support the use of animals in research but want assurance that animals are treated humanely and used only when necessary. Over the years, animal rights activists have exploited this concern for animal welfare and have attempted to impede or stop biomedical research with animals. As a result, some Americans believe that the abuse of laboratory animals is common. Recently, the animal rights movement has been making substantial inroads in obtaining philosophic and financial support for legislation and regulatory changes that would compromise the future of biomedical research.

The activities and arguments of animal rights groups present difficult ethical questions. To accept the philosophic and moral viewpoint of the animal rights movement would require a total ban on the use of animals in biomedical research. The consequences of such a step would certainly slow the pace of health-related research and impede new procedures and technologies from reaching clinical medicine. Laws and regulations directed toward improving the conditions under which biomedical experiments that use animals are conducted have had a measurable impact. The American Medical Association supports regulatory policies enacted to protect animals from unnecessary pain or inappropriate use — however, pain and suffering in human beings will occur if policies advocated by animal rights groups are adopted. Therefore, the American Medical Association believes that what must be recognized and weighed in the balance is the cost of such protection and comfort in terms of human health.

— AMA Council on Scientific Affairs

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50 Years Ago
From the *Journal of the Connecticut State Medical Society*
May 1939

SULFAPYRIDINE

Since the introduction of sulfanilamide chemists have sought for a derivative of this drug which would be as effective against pneumococcal infections as sulfanilamide has proved to be against hemolytic streptococcal diseases. The most promising of these is 2-(para-aminobenzenesulphonamido) pyridine, now generally called sulfapyridine, developed by May & Baker, Ltd., in England and originally reported upon by Whitby.¹ After a period of extensive and well controlled clinical investigations, which appear to indicate that sulfapyridine is of definite therapeutic value in the treatment of pneumococcal infections, particularly lobar pneumonia, at least when used promptly after onset of the disease, sulfapyridine has recently been made available for general use by the profession.

It is important, therefore, that physicians be cognizant not only of the fact that the drug appears to be therapeutically effective in pneumococcal infections but also of the problems encountered in its administration and particularly of the untoward reactions that are to be expected and have been met with in its use.

Although much is yet to be learned concerning the most appropriate dosage, the concentration in the blood necessary for therapeutic effectiveness and the frequency and seriousness of untoward effects, it may be tentatively stated that for adults an initial dose of 2.0 gms. *per os*, followed by 1.0 gms. every four hours, has generally proved satisfactory and within twenty-four hours has established a supposedly desirable blood level of 6 - 10 mgm. per cent. How long the drug should be continued after apparent clinical recovery in order to forestall relapse is uncertain, though a few days with diminishing doses would appear to have been adequate in most instances.

The most frequent problem encountered in administering sulfapyridine *per os* is nausea and vomiting which usually begins very promptly, when it occurs, and has been encountered to a greater or less extent in about 50 per cent of cases. Not only may this prevent the prompt establishment of an adequate concentration in the blood but perhaps 20 per cent of cases be so disturbing as to contraindicate further administration of the drug. Under those circumstances or others which prevent oral administration, the drug may be given by hypodermoclysis in

equal volumes of normal saline and 5 per cent glucose solution.² If 1500 cc. of saline and glucose solution be brought nearly to a boil, 2.0 gms. of pure sulfapyridine powder be added, and the solution be allowed to cool to body temperature, no difficulty is encountered in giving the drug subcutaneously by this method. Two or three treatments every 24 hours seem to maintain an adequate blood level and nausea and vomiting usually stop promptly.

The untoward reactions that may be encountered are in general similar to those met with in the use of sulfanilamide, namely, drug fever usually with a more or less extensive maculopapular morbilliform rash occurring in perhaps 5 - 10 per cent of cases, usually five to eight days after the beginning of treatment; acute hemolytic anemia of uncommon occurrence, and developing within a few days after institution of treatment; acute neutropenia which has been encountered within the first week of treatment; and cyanosis during the treatment, probably of little consequence.

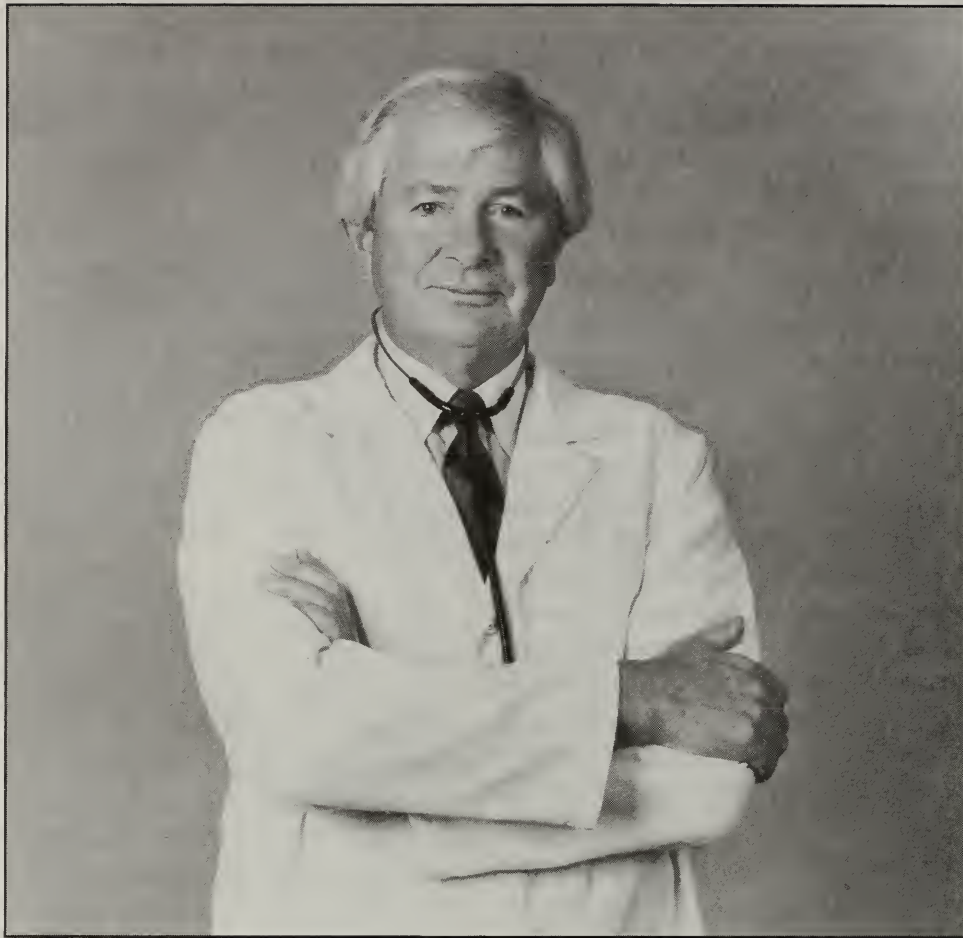
One additional untoward reaction rarely if ever seen with sulfanilamide, is an acute, sudden hematuria which may vary from an asymptomatic, microscopic hematuria to a gross hematuria with fairly severe colic. This may occur in 5 to 10 per cent of patients, appears about the fourth day and lasts for two to five days.

Obviously, the nature and frequency of the untoward reactions require careful supervision of patients under treatment with sulfapyridine in order that the drug may be stopped immediately, when they occur. Under these conditions these reactions would generally, at least, appear to clear up fairly rapidly without any permanent injury. They also clearly indicate that sulfapyridine at present should be limited to the treatment of pneumococcal infections, at least until it is determined whether or not it possesses any advantages not possessed by sulfanilamide in other types of infection. Finally, it would appear too early to abandon the use of antipneumococcal serum in favor of sulfapyridine, until much more extensive experience has determined whether sulfapyridine is comparable to serum in therapeutic effectiveness, particularly in the severer, bacteremic pneumonias.

1. Whitby LEH: *Lancet* 1:1210 (May 28) 1938.

2. Haviland JW and Blake FG: (unpublished observations).

—Editorial by Francis G. Blake, M.D.



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The President's Page

Closing



As I review my year as President of the Society in relation to the goals set forth in my inaugural address, I have the following comments:

- 1.) Tort reform has been a back burner issue this year but has not been forgotten. We have developed background material and an approach to further legislation which could be introduced at an appropriate time. We are also monitoring the AMA proposal and its demonstration projects as an alternative. During the year the Connecticut State Supreme Court initiated a ruling which prevented plaintiffs' attorneys from naming specific amounts of non-economic damages, a step in the right direction. There was almost immediate action in the legislature, and a bill restoring naming amounts of non-economic damages has passed the General Assembly's Judicial Committee and is awaiting a vote.
- 2.) Legislative activity to increase the scope of practice of physical therapists, nurses, and podiatrists has been strong this session. Thus far we have successfully lobbied to control these changes or to continue negotiations where we can. As more states around the country pass similar legislation, such control becomes progressively more difficult. A united effort by all physicians can make these efforts successful. To this end we sponsored two legislative meetings, a symposium and a presidents' dinner which included all specialty sections. From these efforts we found interested physicians who have been very helpful in our lobbying efforts to maintain the quality of patient care.
- 3.) M.D. Health Plan was a significant concern last May. With innovative administrative leadership, however, the HMO and its components are viable and growing. Over 350 new physicians have filled in areas of need making marketing much easier. Enrollees approach 19,000 in total, 15% above projections, and the program is now becoming profitable. It took the emotion of belief in our plan, as well as careful and professional organization. I am proud of M.D. Health Plan's accomplishments, its staff, and the teamwork shown by the physicians on MDEC's Board and that of CSMS-IPA, who meet together monthly and, by their own action, without compensation.
- 4.) The conscious effort by CSMS to communicate better with its county medical association and specialty section components is a continuing effort. I have added key physicians to committees and will set up a new Committee on Allied Health Services in an attempt to develop a better dialogue with physical therapists, podiatrists, optometrists, psychologists, and to avoid the intensely adversarial positions of the past. We already have such a committee interacting with nurses which will continue to be called the Connecticut Joint Practice Committee. These changes will be ratified at the upcoming House of Delegates to become a reality.

All in all, the year has been stimulating, with some successes, some controversies and a few failures. Remaining united will keep the latter to a minimum. Keep the faith.

Norman A. Zlotsky, M.D.
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Reflections on Medicine

A Simpler, Kinder System

ROBERT U. MASSEY, M.D.

In his book, *The American University*, Jacques Barzun writes that the constant aim of the administrator must be, besides making headway, "*simplification*—for the same reason that the householder mows his lawn and prunes his trees."¹ Of course, he was writing of university administrators, presidents, provosts, deans, and department heads, but the university, as its name suggests, is a small world governed by the same politics that move the Wide World. And its legislators, the faculty, are, outside their laboratories and classrooms, not at all unlike the real legislators in the state houses and national capitals; Barzun records the remark of a Cambridge scientist, part of which applies to legislators as well as faculty members: "We're all terribly clever—but silly!"²

Once again the issue of national health insurance is up for serious debate. Over the past decade or so we have done everything to complicate rather than simplify our management of medical care, and the results have been not only terribly expensive, inefficient, and cruel, but, most damning of all, silly. My immersion in a backwater of this silliness came 10 years ago when we were seeking a certificate of need for a computed tomographic scanner for the university hospital. Four or five academic and hospital administrators spent the greater part of their time for over a year acting out a silly play whose last scene we all knew before we started; as the only university hospital without a scanner, we knew we would win, but the bureaucrats were bent upon spending a million dollars of the taxpayers' money and wasting our time for their *opera comique*.

Now in this matter of health insurance, we all know that a just society will someday find a way to pay for medical care for all its members, that we will not continue to live with one fourth of the nation uninsured, and that we cannot continue to sustain medical care costs that are running far ahead of inflation and taking an ever increasing percentage of the gross national product. Most of us shudder, however, to contemplate the contraption our political masters are likely to put together to solve the problem. We see their handiwork all about us. Already hospital administrators spend more time trying to survive in an absurd system of regulations and regula-

tors than in tending their shops, and doctors spend their days in justified, and sometimes disabling, rage against a host of nonproductive bureaucrats whose unfortunate task is to frustrate them at every turn.

In the midst of what is now admitted to be an honest-to-goodness crisis (we've had crises in medicine for as long as I can remember), some of our colleagues have suggested that we look seriously at the Canadian model. It does indeed have many virtues, not the least of which is its seeming simplicity. Hospitals for example are not micromanaged by amateurs; budgets are negotiated in advance and the hospital directors are actually allowed to use their skills to do the best they can with the means at hand, which is what management is all about. Of course, the Canadian-style system would discontinue all forms of health insurance except for the single universal system; that might eliminate 10% or 12% of unproductive health care costs. Physicians negotiate fee levels, but are otherwise free to practice medicine rather than spending their time dealing with dozens of different organizations each with its separate rules and bureaucracy.

The Canadian system is far from perfect; perfection is not achievable in this life, and is a nonsense word when applied to human systems. By all accounts, including the patients' view, it is better than ours. Before we undertake another major tampering job with a structure already collapsing under its own weight of complexity, we should look very seriously at the other North American way of paying for medical care. Three states, according to *American Medical News*³ are already considering bills for a Canadian-style system—Ohio, Michigan, and Wisconsin. It would be good to experiment but unfortunate if we were to develop 50 different systems; one of the virtues of national health insurance in Canada is its portability throughout all the provinces.

It is almost always said, when the subject comes up, that the Canadian system would not work here—said so often in fact that we may come to believe it. I asked a group of nonphysicians, lawyers and businessmen mostly, why this is so; one answered, "Canada is a kinder, gentler nation," and the others seemed almost to agree.

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1. Barzun J: *The American University*, New York, Harper Colophon Books, 1970, pp 132.
2. Ibid, p. 130 (n).
3. 7 April 1989.

ROBERT U. MASSEY, M.D., Professor, Division of Humanistic Studies in Medicine, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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Examining the *McConnell* Decision

JOSEPH M. HEALEY, J.D.

THE majority opinion of Chief Justice Peters in the *McConnell* decision¹ disappointed many supporters on both sides of the issues at stake in the case. Opponents who had argued that relevant statutory provisions prohibited the requested relief or, in the alternative, that the facts in the case did not support allowing artificial nutrition and hydration to be removed, sought reversal of the lower court decision and were disappointed by the outcome. Some proponents, while pleased with the outcome, have complained that the Chief Justice should have more clearly articulated a common law and constitutional law basis for holding the relevant statutes unconstitutional and for affirming the right to refuse treatment. In last month's column, I discussed the framework relied upon by the Chief Justice and by Justice Healey in his concurring opinion. This month's column will continue the discussion of the case and its implications.

Among the questions of fact reviewed by the Supreme Court were three challenged on the ground that there was insufficient evidence to support the findings of the lower court: (1) that the patient was in a terminal condition; (2) that proper consent had been obtained from next of kin; and (3) that the patient's wishes had been expressed with sufficient clarity to permit actions by her surrogates. In each case, the Supreme Court affirmed the lower court's decision. In the first example, the issue involved the statutory definition of "terminal condition" and the manner in which such a determination is made. Under the relevant statute, terminal condition is defined as "the final stage of an incurable or irreversible

medical condition which, in the opinion of the attending physician, will result in death."² The Supreme Court emphasized the central role of the attending physician in such determination: "While there was testimony to the contrary on this issue, the act places the responsibility for reaching the conclusion with the attending *physician*, contemplating a decision to discontinue treatment reached after consultation between the attending physician and the family or next of kin, unimpeded by courts, other medical experts or ethicists."¹ (p.707) The Supreme Court found nothing in the record to justify overruling the lower court finding.

The second and third issues were easily handled by the Supreme Court which emphasized the strong evidence upon which the trial court's conclusions were based. There was unanimity within the family about the removal of the feeding tube and no evidence of ulterior motive on the part of any family member. Ms. McConnell's work experience and her conversations with family and co-workers supported the conclusion that she understood the full range of technology available to sustain life and had expressed her wish not to have her life sustained by its use.

While the *McConnell* case did not answer as many questions as some observers had hoped, it has provided an important foundation for further consideration of these issues. Discussion of this foundation will continue next month.

REFERENCES

1. *McConnell v. Beverly Enterprises-Connecticut, Inc.* 209 Conn. 692 (1989).
2. Connecticut General Statutes Sec. 19a-570(3).

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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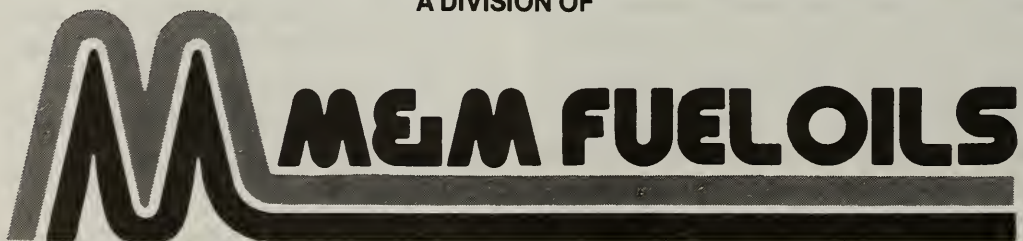
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Introduction

Lyme Disease

MATTHEW L. CARTTER, M.D.

Guest Editor

AS a medical epidemiologist working for the Connecticut Department of Health Services, it is common for me to hear that physicians in Connecticut do not know enough about Lyme disease. When I reply that Connecticut physicians probably know more about Lyme disease than physicians elsewhere, few are comforted.

In the summer of 1986, I received my first phone call from Mrs. Polly Murray, one of two mothers from Lyme who brought this disease to the attention of physicians in 1975 (Mrs. Murray's story is told in part in Mr. Lang's history of Lyme disease that appears in this issue). Mrs. Murray told me that physicians needed to be educated about Lyme disease (she has a way of pointing out unrecognized problems). But how does one educate a physician?

In October 1988, Dr. Robert Massey, the editor of *Connecticut Medicine*, chaired a workshop entitled "Educating Physicians: What Works; What Doesn't" at a conference for Lyme disease educators (Pfizer Central Research, Groton, Connecticut). The idea for this special issue of *Connecticut Medicine* on Lyme disease took shape at that workshop. The premise is that Connecticut

physicians need a current, practical, and reasonably concise source of information on Lyme disease. The key to educating physicians is helping physicians educate themselves.

I would like to thank the staff of the Epidemiology Program of the Connecticut Department of Health Services and the members of the Lyme Disease Awareness Task Force of the Connecticut Chapter Arthritis Foundation for their support and encouragement. I would like to acknowledge Dr. James Hadler, Dr. Michael Gerber, Dr. Thomas Farley, and Patricia Mshar for their help in reviewing manuscripts. I would like to thank Dr. Robert Massey and the staff of *Connecticut Medicine* for making this issue possible. Most importantly, I would like to thank the authors, most of whom are from Connecticut. Connecticut has been, and should continue to be, a center of Lyme disease research and scholarship.

A year ago, a physician friend of mine attended a Lyme disease conference. Later she told me that her concern about Lyme disease had turned to dread as the conference had progressed. Lyme disease has a way of forcing us to confront the limitations of medical science more than we are accustomed, and definitely more than we would like. This special issue of *Connecticut Medicine* is intended to assist physicians in the clinical management of their patients with Lyme disease and to encourage physicians to educate their patients about this growing problem.

MATTHEW L. CARTTER, M.D., Epidemiology Program Coordinator, State of Connecticut Department of Health Services, Hartford, CT; Assistant Clinical Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT; Member of the Lyme Disease Awareness Task Force, Connecticut Chapter Arthritis Foundation.

The Epidemiology of Lyme Disease in Connecticut

MATTHEW L. CARTTER, M.D., PATRICIA MSHAR,
AND JAMES L. HADLER, M.D., M.P.H.

ABSTRACT—The overall incidence for Lyme disease for Connecticut residents in 1988 was 22 per 100,000. The highest rates were among residents of New London (108 per 100,000) and Middlesex Counties (72 per 100,000), although the greatest increase in incidence between 1985 and 1988 occurred among residents of Fairfield County (2 per 100,000 in 1985, 14 per 100,000 in 1988). Lyme disease is a statewide problem; in 1988 cases were reported among residents of 104 of Connecticut's 169 towns and cities. The disease burden in some communities is high with case rates approaching 1% of the population per year. Data from 1977 and 1985 suggest a three- to eightfold increase during that period in the occurrence of Lyme disease in the communities near the mouth of the Connecticut River. Continued reporting of cases with supporting clinical information is needed to improve Lyme disease surveillance and establish disease trends.

IN 1975 an epidemiologist at the Connecticut State Department of Health and a rheumatologist, who was also an epidemiologist, at the Yale University School of Medicine were notified of an unusual cluster of cases of arthritis occurring in children in Lyme, Connecticut. The epidemiologic studies of Lyme disease that followed suggested an infectious etiology¹ and later led to the discovery of the tick vector *Ixodes dammini*.² The epidemiology of Lyme disease continues to provide a measure of the relative geographic distribution of this disease and its public health impact on the citizens of Connecticut.

This paper will review the epidemiology of Lyme disease in Connecticut and discuss the current surveillance

system for the disease. The epidemiologic studies reviewed come primarily from three sources over three time periods: 1) epidemiologic studies and active surveillance from 1975 to 1983, 2) laboratory-based surveillance during 1984-1985, and 3) passive, physician-based reporting which began in July 1987.

The Early Years, 1975-1983

Steere et al conducted their initial retrospective study of Lyme arthritis from December 1975 through May 1976.¹ The study involved 51 residents (39 children and 12 adults) of Old Lyme, Lyme, and East Haddam (total population, 12,000). The onset of arthritis in the 51 patients occurred from July 1972 through May 1976. The overall period prevalence rate was 4.3 per 1,000 residents; a rate of 12.2 per 1,000 for children and 1.4 per 1,000 for adults.

In 1977 Steere et al conducted a prospective study of Lyme disease.² The active surveillance system that they created in 1975 was expanded to include cases of erythema migrans (EM) in addition to arthritis. Nine communities to the west of the Connecticut River were surveyed in addition to Old Lyme, Lyme, and East Haddam on the eastern shore. Cases were found by contacting the 33 physicians and four visiting nurse associations practicing in these communities and by contacting selected physicians, usually specialists who were likely to see patients with Lyme disease, in additional communities. Of the 43 cases identified, 38 had EM and five had oligoarticular arthritis. Case rates are shown for 1977 (Table 1). The overall incidence of the illness was 2.8 cases per 1,000 residents on the east side of the Connecticut River (35/12,400) compared to 0.1 cases per 1,000 residents on the west side (8/60,300).

In May - November, 1987, epidemiologists from the Connecticut State Department of Health and the Federal Centers for Disease Control studied the occurrence of EM and Lyme arthritis in children in New London County, east of the original three-town epidemic focus, and in Litchfield County in northwest Connecticut.³ The study was designed to complement the study conducted by Steere et al² and used a similar protocol to identify

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cases prospectively. The case rate was 0.15 cases per 1,000 residents under 18 years of age in New London County outside the epidemic focus. This rate was nearly 30 times lower than the rate estimated by Steere et al for the population under 18 from Lyme, Old Lyme, and East Haddam (4.4 per 1,000). No cases were identified in Litchfield County.

Steere and Malawista summarized the data on known Lyme disease cases in 1979.⁴ From November 1975 through August 1979, a total of 388 cases of Lyme disease in Connecticut residents had been brought to their attention. For Old Lyme, Lyme, and East Haddam, the three communities that had been under continuous active surveillance for four years, 242 cases had been reported for an estimated cumulative frequency of 2% of residents.

In 1981 the Centers for Disease Control (CDC) published a report on Lyme disease that tabulated cases occurring in 1980.⁶ Of the 133 reported cases in Connecticut residents, 106 were detected through Yale University's active case finding efforts in the Lyme area.

National surveillance for Lyme disease was formally established in 1982.⁶ In 1982, 135 cases were reported in Connecticut residents; in 1983, 78 cases were reported.⁷ These cases were reported primarily through CDC review of data from the Lyme disease clinic at the Yale University School of Medicine. During this period, it became more difficult to use the data from Yale to evaluate

incidence trends because the Yale investigators had shifted their research focus to patients with late rather than early Lyme disease.

Laboratory-Based Surveillance, 1984-1985

The State of Connecticut Department of Health Services (CDHS) conducted a laboratory-based program of surveillance for Lyme disease from July 1, 1984 to March 1, 1986. Serologic testing was offered to Connecticut physicians without cost for all residents with suspected Lyme disease if the serum was accompanied by a case report form. A summary of this study was published in 1988 by the Centers for Disease Control (CDC).⁸

The CDC case definition for Lyme disease acquired in endemic areas was used to classify cases.⁷ Residents were counted as cases if they had a) EM regardless of serologic results or b) neurologic, cardiac, or arthritic manifestations characteristic of Lyme disease and a positive serologic test for antibody to *Borrelia burgdorferi*. Thirty-seven percent of the 3,098 persons tested met the case criteria (460 in 1984 and 689 in 1985). Overall, 83% of those reported had EM; 24% had arthritis, 8% had neurologic manifestations, and 2% had cardiac involvement. The incidence of Lyme disease for all Connecticut residents in 1985 was 22 per 100,000. Case rates by 10 year age groups and by county are given in Tables 2 and 3 respectively. Town-specific case rates ranged from zero to 12 per 1,000. Among the 12 communities studied by Steere et al,² case rates increased three- to eightfold

Table 1
REPORTED LYME DISEASE CASE RATES
IN 12 COMMUNITIES IN CONNECTICUT FOR 1977, 1985, AND 1988

Town	1977*		1985		1988	
	No. of Cases	Rate/1000 Residents	No. of Cases	Rate/1000 Residents**	No. of Cases	Rate/1000 Residents**
East of Connecticut						
River						
Old Lyme	11	2.0	59	9.2	51	7.6
Lyme	5	2.9	28	14.1	16	8.1
East Haddam	19	3.7	25	4.1	39	5.9
Total	35	2.8	112	7.7	106	6.9
West of Connecticut						
River						
Old Saybrook	1	0.1	8	0.8	3	0.3
Essex	4	0.8	11	2.1	3	0.5
Deep River	0	0	5	1.2	2	0.5
Chester	1	0.3	7	2.2	2	0.6
Haddam	0	0	4	0.6	8	1.2
Westbrook	0	0	5	0.9	1	0.2
Clinton	2	0.2	12	1.0	6	0.5
Killingworth	0	0	4	0.9	0	0.0
Madison	0	0	8	0.5	9	0.6
Total	8	0.1	64	1.0	34	0.5

* From Steere et al.²
** 1985 and 1988 population estimates, Connecticut Department of Health Services.

compared to 1977 (Table 1). The highest rates were still in communities east of the Connecticut River.

Physician-based Surveillance, July 1987 - Present

Since July 1987, physicians in Connecticut have been required to report cases of Lyme disease to the State and local health departments. At that time, letters were sent to all licensed physicians to notify them of the reporting requirement and the surveillance case definition. Because the clinical information needed to classify a case is not part of the standard communicable disease report form used in Connecticut, two classes of Lyme disease cases were established: 1) cases reported with sufficient clinical information to meet the CDC case definition and 2) cases reported by physicians without clinical information. Case totals for Connecticut, tabulated by CDHS, include both case classes, while statistics for Connecticut published by CDC include only those cases meeting the CDC case definition.

Table 2
REPORTED LYME DISEASE CASES, BY 10 YEAR AGE GROUP, CONNECTICUT, 1985 and 1988

Age	1985		1988	
	No. of Cases	Rate/100,000 Residents*	No. of Cases	Rate/100,000 Residents*
0-9	116	30	150	36
10-19	76	16	90	21
20-29	77	13	72	13
30-39	121	24	95	18
40-49	83	22	72	18
50-59	74	22	66	20
60-69	59	18	68	21
70+	38	14	44	14
Unknown	45	—	3	—
Total	689	22	728	22

* 1985 and 1987 population estimates, Connecticut Department of Health Services.

In the last six months of 1987, 212 cases were reported, of which 157 (74%) were reported by physicians without clinical information. Of the 55 (26%) cases that met the CDC clinical case definition, EM occurred in 42 cases, and a systemic manifestation and a positive serologic test for antibody to *B. burgdorferi* were found in 13 cases.

In 1988, 728 cases were reported, of which 366 (74%) cases were reported by physicians without clinical information. Of the 362 cases that met the clinical case definition, EM occurred in 281 cases, and a systemic manifestation and a positive serologic test for antibody to *B. burgdorferi* were found in 81 cases. Among the cases reported with clinical information, the relative proportion with EM (78%) was similar to 83% obtained in 1985 from laboratory-based surveillance. Arthritic symptoms occurred in 50 (14%), neurologic manifestations occurred in 38 (10%), and cardiac complications occurred in four (1%) cases. Some cases had more than one systemic manifestation. The relative frequency of arthritic, neurologic, and cardiac manifestations was similar to that obtained from laboratory-based surveillance.

Onset dates were provided for 441 (61%) of reported cases. Three hundred thirty cases (75%) reported symptoms onset during the summer months of June, July, or

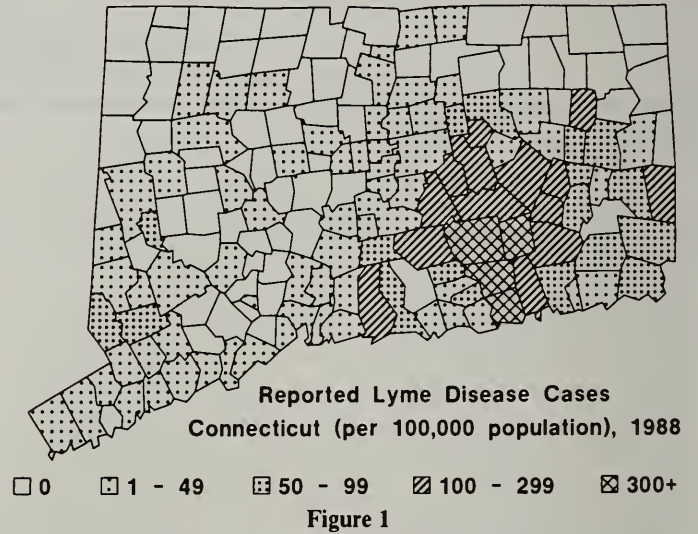
August with the lowest incidence occurring during the month of February (0%). Fifty-one percent of patients with Lyme disease were male, and all but six of the 488 patients with known race were white. Children aged 0-9 had the highest incidence (36 per 100,000) of any age group (Table 2).

In 1988 the overall incidence rate for Connecticut was 22 per 100,000 population (Table 3). The highest rates were among residents of New London (108 per 100,000) and Middlesex Counties (72 per 100,000). The greatest rate increase between 1985 and 1988 occurred among residents of Fairfield County (2 per 100,000 in 1985, 14 per 100,000 in 1988).

Cases were reported among residents of 104 of the state's 169 towns and cities. Statewide town-specific rates are shown in Figure 1. Rates for the 12 communities originally studied by Steere et al⁴ are shown in Table 1. Case rates with physician-based reporting were similar to those determined from laboratory-based reporting in 1985, and continued to show large increases compared to 1977. The communities east of the Connecticut River continued to have the highest reported case rates.

Discussion

Epidemiology, the science of public health, is the study of the occurrence of disease within populations and the factors that determine its spread.⁹ Surveillance is a type of observational study that involves the continuous monitoring of disease occurrence within a population and is used to establish long-term trends and patterns of disease occurrence.¹⁰ Knowledge of the epidemiology of Lyme



disease is needed to guide and evaluate control measures and public health education efforts.

Surveillance systems for Lyme disease in Connecticut have changed considerably over time. Nonetheless, the results from each form of surveillance have shown similar geographic and age-related distributions within Connecticut. This suggests that the current reporting system will be an effective way to monitor Lyme disease in Connecticut. Surveillance has also confirmed a high disease burden, especially in communities where the incidence rates approach 1% of the population per year. Given that arthritic, neurologic, or cardiac complications are present in nearly a quarter of reported cases,

Lyme disease has become a major health concern in these communities.

The changing forms of surveillance and their different levels of sensitivity and specificity make it difficult to determine conclusively whether Lyme disease is becoming more common in Connecticut. However, the data from 1977 and 1985, when active surveillance of cases

Table 3
REPORTED LYME DISEASE CASES, BY COUNTY,
CONNECTICUT, 1985 and 1988

County	1985		1988	
	No. of Cases	Rate/100,000 Residents*	No. of Cases	Rate/100,000 Residents*
New London	350	141	277	108
Middlesex	102	76	104	72
Tolland	32	27	36	28
Windham	15	16	19	19
Fairfield	19	2	118	14
New Haven	28	4	75	9
Litchfield	9	6	14	8
Hartford	59	7	59	7
Unknown	75	—	26	—
Total	689	22	728	22

* 1985 and 1987 population estimates, Connecticut Department of Health Services.

assured a reasonably high level of sensitivity, suggest a great increase in the incidence of Lyme disease in the communities near the mouth of the Connecticut River with case rates increasing three- to eightfold during that period.

By the mid-1980s, the disease had spread inland from the coastal areas.⁸ Cases of Lyme disease were reported from Litchfield County in northwestern Connecticut in both 1985 and 1988, in contrast to the finding of no cases, at least among children, by Kaslow et al in 1977.³ The tick vector *Ixodes dammini* was found in Litchfield County for the first time in 1988 according to L.A. Magnarelli, Ph.D. (personal communication, May 1989). The dramatic increase in the case rate among residents of Fairfield County in the southeastern part of the state between 1985 and 1988 is probably due to a combination of improved reporting and a true increase in incidence. Fairfield County borders on Westchester County, a highly endemic area in New York.

While no areas of the state are free of the risk of Lyme disease, some areas are more affected than others. In 1985, 26% (176/689) of the cases reported occurred inside the 12-town area around Lyme compared to 19% (140/728) in 1988. This finding may be due in part to increased recognition of the disease in the southeastern part of the state. Continued monitoring with the current reporting system should provide better information on whether and where increases are occurring.

Underreporting of disease is a major limitation of passive surveillance systems such as the physician-based system now used in Connecticut for Lyme disease.¹⁰ Reporting generally becomes less complete as the disease reported becomes more common, especially if that disease is largely managed in the outpatient setting. For the more common outpatient diseases, only 10% to 25% of the actual

number of cases occurring in a community may be reported.^{10,11} In general, reporting can be improved with a laboratory-based surveillance component.^{12,13} The problem with using reported test results for laboratory-based surveillance for Lyme disease is that the current serologic test is often not reactive in early Lyme disease, and once reactive, it may remain so for months to years. Clinical information from the physician is still needed to classify cases. When a more definitive diagnostic test is developed, laboratory-based reporting for Lyme disease will become more practical and meaningful.

Consistent reporting by physicians over several years will be necessary for data from the current surveillance system to be useful for evaluating trends. Better reporting of clinical information is needed to improve the specificity of the system and increase the percentage of cases reportable to CDC. The physician has the key role in effective surveillance of Lyme disease. When reporting, the physician should clearly indicate symptoms and serologic results (if available) in addition to patient's name, town of residence, age, and date of onset. A standard form, known as the Communicable Disease Report (PD-23), is available for reporting Lyme disease. This form may be obtained from the State of Connecticut Department of Health Services, Epidemiology Program, 150 Washington Street, Hartford, CT 06106; telephone: (203) 566-5058. Surveillance summaries will be published periodically in the *Connecticut Epidemiologist*.

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National Surveillance of Lyme Disease, 1987-1988

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ABSTRACT—In 1987 and 1988, 6876 Lyme disease cases from 43 states were reported to the Centers for Disease Control. The 4507 cases reported in 1988 was nearly double the case number reported in 1987, and ninefold the number reported in 1982, when a systematic system of national surveillance was established. The average annual incidence of reported Lyme disease in the United States in 1987-1988 was 1.4/100,000. New York led the nation in reported cases in 1988 with 57% of the cases reported nationally. Eight states, New York, New Jersey, Pennsylvania, Connecticut, Massachusetts, Rhode Island, Wisconsin, and Minnesota, reported 92% of the nation's cases. The state reporting the highest incidence rate in 1987-88 was Rhode Island, with 9.9 cases/100,000. Regionally, incidence rates were highest in Northeastern and Mid-Atlantic states, intermediate in North Central and Pacific states, lower in the Southeast, and lowest in the Great Plains and Mountain states. The seven remaining states in which Lyme disease has not been transmitted all lie west of the 100th meridian.

SINCE 1975, when it was recognized as a cause of S arthritis in Connecticut,¹ Lyme disease has emerged from a local concern to become a public health problem of a national scale. National surveillance of Lyme disease was established at the Centers for Disease Control (CDC) in 1982, and in the 7-year interval to the present, approximately 13,500 cases have been reported.²⁻⁴ Preliminary national surveillance statistics from 1987 and 1988 are reviewed in this paper.

Methods

Cases of Lyme disease are reported to CDC from state health departments. Reporting patterns vary from state to state and depend on physician awareness of Lyme disease, customary reporting practices, whether Lyme disease is legally reportable in a state, and the extent to

which state health departments are able to actively identify suspected cases. Ultimately, the completeness of reporting depends on the faithfulness with which clinicians report cases to their local health departments.

Cases of Lyme disease reported by CDC between 1983-86 were identified from case report forms accompanying diagnostic serum samples submitted to CDC, from case report forms submitted by states, and from a survey of states to confirm the number of cases known to state health departments. From 1983-1986, completed case report forms were available from only 31% of the total cases reported to states.^{3,4} Consequently, the national surveillance summary of cases in 1983-1986 largely reflected cases found through a survey of state health departments. To obtain national statistics on the occurrence of Lyme disease in 1987 and 1988, we used a similar approach. We asked state health departments through mail, telegram, and telephone surveys to report Lyme disease cases acquired in the state and reported in 1987 and 1988. In most instances, the year of onset of Lyme disease was identical to the year of report. However, because Lyme disease may have chronic features and the diagnosis may not be entertained or confirmed for months or even years after the onset of illness, reported cases are a reflection of prevalent cases as well as newly acquired cases. Over 90% of cases reported to CDC between 1983-1986 had erythema migrans (EM), a hallmark of early Lyme disease. Therefore case rates can be regarded in large measure as an index of incidence and these rates are reported as incidence rates in this publication. An epidemiologic analysis of data from case report forms from these two years will be the subject of a separate publication.

The case definition of Lyme disease used by most states conforms to the current CDC definition: 1) in the event of exposure in an endemic county, a patient with EM alone meets the requirement for inclusion as a case; 2) in the event of exposure in a nonendemic county, EM must be accompanied by laboratory evidence of infection with *Borrelia burgdorferi* for inclusion as a case. The definition, adopted in 1988, is not used uniformly by

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state health departments, and some states (e.g. New York and Wisconsin) continue to use the broader definition adopted in 1983, which also includes as cases, patients without EM but who have characteristic findings of Lyme disease involving the joints, heart, and nervous system.^{3,4} For the purpose of this report, cases meeting either definition were included.

State population figures for 1987 were obtained from U.S. Bureau of Census estimates.⁵

Results

In 1987 and 1988, 6876 Lyme disease cases were reported to CDC (Table 1). The 4507 cases reported in 1988 was nearly double the number reported in 1987 and nine-fold the number of cases reported in 1982. The average annual incidence of Lyme disease in the nation for 1987-1988 was 1.4/100,000.

Transmission of Lyme disease now has been reported in 43 states. Since the surveillance period ending in 1986, 11 additional states have reported indigenous cases. These states are chiefly from the Southeast (Louisiana and Mississippi), the Midwest (Iowa, Kansas, North Dakota, and South Dakota), the West (Colorado, Idaho, and Washington), and also Vermont and West Virginia.

The region reporting the highest incidence of Lyme disease was the three-state Mid-Atlantic region (New York, New Jersey, and Pennsylvania) (Table). New York led the nation in reported cases in 1988, with 2553,

more than half of the cases reported nationwide. The average annual incidence for the state for 1987-1988 was 9.6/100,000, second in the nation. Although county data are not available to CDC at this time, cases in two New York counties, Suffolk and Westchester counties in downstate New York, accounted for 77.5% of the cases in the state and approximately 44% of the cases reported nationally (personal communication, D. White).

The state reporting the highest incidence of Lyme disease in 1987-1988 was Rhode Island, with 9.9 cases/100,000. The Northeast region, encompassing Connecticut and the five states north of it, reported an incidence of 3.7/100,000, second in incidence to the contiguous Mid Atlantic region.

In the interior of the nation, only Wisconsin and Minnesota reported large numbers of cases and rates above 1/100,000 (6.3 and 1.9/100,000 respectively). Elsewhere in the North Central region, only sporadic cases were reported and incidence rates were considerably lower.

Although Lyme disease now has been recognized in all of the southeastern states, incidence rates in the Southeast were consistently low, reflecting the sporadic transmission pattern seen in these states. The average annual incidence rate for 1987-1988 for the District of Columbia and the 16 states in the East South Central, West South Central, and South Atlantic regions was 0.2/100,000 (0.14-0.22/100,000, 99% confidence interval under a

Table 1
REPORTED LYME DISEASE, 1980-1988 UNITED STATES BY REGION

Region	1980	1982	1983	1984	1985	1986	1987	1988	Total	Incidence*	99%
											Poisson C.I.
East North Central	24	49	66	183	168	238	372	294	1394	.79	.67 - .91
East South Central	0	0	1	1	5	2	4	29	42	.11	.05 - .20
Mid-Atlantic	18	266	481	986	804	693	1199	3359	7806	6.09	5.76 - 6.42
Mountain	1	1	1	0	0	1	0	5	9	0.02	.01 - .07
Northeast	66	179	112	536	810	231	384	573	2891	3.73	3.30 - 4.18
Pacific	1	4	7	35	89	145	213		494	0.61**	.51 - .72
South Atlantic	2	2	10	35	54	38	62	137	340	0.24	.18 - .31
West North Central	8	22	55	86	66	94	98	74	503	0.49	.36 - .64
West South Central	0	0	2	22	172	11	37	36	280	0.14	.08 - .20
TOTAL	120	523	735	1884	2168	1453	2369	4507	13759	1.42	

* Average annual incidence/100,000 for 1987-1988 (see text)
** Annual incidence/100,000 for 1987

- East North Central:
- East South Central:
- Mid Atlantic:
- Mountain:
- Northeast:
- Pacific:
- South Atlantic:
- West North Central:
- West South Central:
- Illinois, Indiana, Michigan, Ohio, Wisconsin
- Alabama, Kentucky, Mississippi, Tennessee
- New Jersey, New York, Pennsylvania
- Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
- Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
- California, Oregon, Washington
- Delaware, Dist. of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
- Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
- Arkansas, Louisiana, Oklahoma, Texas

Poisson Distribution).

West of the 100th meridian, Lyme disease remains a rare disease, except on the Pacific coast. The remaining seven states in which transmission of Lyme disease has not been recognized, all lie in the Great Plains, Mountain and Pacific regions: Nebraska, Montana, Wyoming, New Mexico, Arizona, Hawaii, and Alaska. Fewer than two cases have been reported each year from the Mountain states, resulting in the lowest incidence rates for any region in the nation.

The annual incidence rate for 1987 for the three states lying on the Pacific Coast, California, Oregon, and Washington, was 0.61/100,000 (0.51-0.72/100,000, 99% confidence interval under a Poisson distribution). Incidence rates in California and Oregon in 1987 were not significantly different, 0.66 and 0.84/100,000 respectively.

Discussion

National surveillance statistics from 1982, 1983-1986, and the current period, 1987-1988, show a progressive increase in reported cases of Lyme disease. The number of cases reported annually has increased, by ninefold since 1982. The rising incidence of Lyme disease undoubtedly is due both to increased recognition and better reporting of the disease and to a real increase in disease transmission. Longitudinal, community-based surveillance in endemic regions in the Northeast has documented secular trends toward increasing incidence and geographic spread of the disease in Connecticut,⁶ Massachusetts,^{7,8} and New York (personal communication, D. White). Data from entomologic surveys support these epidemiologic observations. Increases in the populations of *Ixodes dammini* in established foci and the vector's spread north and south along the Atlantic Coast, apparently to new ranges, have been documented by systematic field surveys.⁹

Although transmission of Lyme disease now has been reported from 43 states, 80% of the cases reported nationally in 1987-1988 were from the six mid-Atlantic and northeastern states of New York, New Jersey, Pennsylvania, Connecticut, Massachusetts, and Rhode Island. With the addition of cases reported from Wisconsin and Minnesota, 92% of the cases reported nationally could be accounted for from eight states. Although the incidence of Lyme disease remains highest in these eastern states, state-based incidence figures belie the intensity of transmission in certain townships and counties in this region, where local incidence figures over 1/1000 have been measured.^{6-8,10}

The low incidence rates and sporadic pattern of transmission in the Southeast and on the Pacific Coast undoubtedly reflect differences in the vectors and vector ecology in these regions. Infection rates in *I. scapularis*, *I. pacificus*, and *I. dammini* in the Southeast, Pacific Coast, and the Northeast differ roughly by tenfold increments, from 0.4% to 4% and 40%.^{9,11,12} Incidence rates in the 16 states in the Southeast (see above), 0.18/100,000; the

Pacific Coast, 0.61/100,000; and the Mid-Atlantic-Northeast, 3.7-6.1/100,000, stand in parallel to the trend of reported infection rates in vector *Ixodes* ticks. It is unlikely that this single factor explains regional differences in the numbers of reported cases. Other epidemiological and biological differences, as well as artifacts of reporting, clearly may contribute to these variations. These considerations notwithstanding, in the surveillance of other vector-borne diseases, such as mosquito-borne arboviral encephalitis, infection rates in vectors are one of the best and most useful measures of the risk of disease transmission to humans. Further studies are needed to determine how local variations in infection rates of vector ticks affect human risk of acquiring Lyme disease.

These statistics on the national occurrence of Lyme disease should be interpreted with an understanding of the limitations of passive reporting. These limitations are not unique to the Lyme disease surveillance system and affect reporting of virtually all diseases. Lyme disease undoubtedly is underreported, but the value of a national surveillance system is not compromised by this acknowledged shortcoming. The formation of public health policy depends on a consistent system of national surveillance that provides essential information on secular trends in disease occurrence and the geographic distribution of cases, and insights into regional differences in disease transmission.

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Clinical Manifestations of Lyme Disease in the United States

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Introduction

LYME disease is a tick-borne infectious disease caused by the spirochete, *Borrelia burgdorferi*.¹ In Connecticut, and other states in the northeastern United States, the disease is most commonly transmitted by the tiny deer tick, *Ixodes dammini*. This tick typically feeds unnoticed for many hours allowing sufficient time to transmit spirochetes from its gut to human skin at the site of a bite. Spirochetes then migrate outwardly in the skin causing the unique expanding skin lesion, erythema migrans. Subsequent hematogenous dissemination of spirochetes to secondary sites may cause major organ system involvement.

Lyme disease often is described as occurring in three stages. The illness begins with erythema migrans and associated flu-like symptoms (stage 1). Weeks to months later stage 1 illness may be followed by acute neurologic and cardiac disease (stage 2), and then months to years later by arthritis and chronic neurologic disease (stage 3). Considerable overlap exists among these stages, however, such that Lyme disease is best characterized as an illness which evolves from early to late disease without reference to an arbitrary staging system.

Cutaneous Manifestations

The cutaneous manifestations of Lyme disease can be divided into early (erythema migrans), secondary (disseminated lesions and lymphocytoma), and late lesions (acrodermatitis chronica atrophicans). With the exception of the latter, these cutaneous manifestations generally resolve spontaneously over weeks to months. The early and secondary cutaneous lesions can be effectively treated with antibiotics, as can acrodermatitis chronica atrophicans.

Erythema Migrans and Early Disease

Erythema migrans, the unique skin lesion of early Lyme disease, develops several days to one month after infection with *B. burgdorferi* in approximately two-thirds of patients. This lesion first appears as a red papule

at the site of the tick bite. An expanding area of erythema around the bite develops over days to weeks, attaining a median diameter of 15 cm, although lesions with a diameter of up to 68 cm have been reported. Central fading within the erythema typically gives erythema migrans a ring-like appearance. The lesion is often flat and may be asymptomatic, but tender, warm, or pruritic lesions are also quite common. Although the bite (and subsequent erythema migrans) may occur anywhere, the tick has a predilection for the thigh, groin, or axilla. Facial erythema migrans is more common among children. Atypical forms of erythema migrans occur: early lesions may have indurated or vesicular centers, or mimic streptococcal or staphylococcal cellulitis. Central necrosis also may occur and be misdiagnosed as a bite of the brown-recluse spider.² Rarely, transient eruptions are seen in early Lyme disease, and include maculopapular rashes, urticaria, malar rash, septal panniculitis (erythema nodosum),³ and/or localized granuloma annulare. Although *B. burgdorferi* has been isolated from the perimeter of erythema migrans, skin biopsy for diagnosis is a low-yield procedure. Histologically, erythema migrans has a non-specific appearance with a perivascular infiltrate comprised of lymphocytes, plasma cells, eosinophils, and histiocytes.

In addition to erythema migrans, many patients with early disease will have a flu-like syndrome characterized by fatigue, fever, malaise, headache, arthralgias, myalgias, regional or generalized lymphadenopathy, and/or conjunctivitis.⁴ One-third of patients will have such symptoms in the absence of erythema migrans. These symptoms are typically intermittent and changing, with the exception of fatigue, which is often persistent and may be debilitating. Right upper-quadrant tenderness and a mild hepatitis may occur (hepatitis also has been reported in later disease)⁵, as well as rare cases of myositis⁶ and adult respiratory distress syndrome.⁷ During this early phase of disease, laboratory findings are nonspecific and typically may include elevated sedimentation rates, elevated serum IgM levels, and mildly elevated hepatic transaminases; the latter supports the notion that hepatitis may be a feature of early Lyme disease. Specific IgM or IgG antibodies against *B. burgdorferi* are usually not

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detectable in serum unless symptoms have been present for at least two to four weeks.

Secondary Lesions

Several days to weeks after onset of erythema migrans, nearly one-half of untreated patients develop secondary skin lesions. These annular lesions resemble erythema migrans, but they expand less, are generally smaller, and lack indurated centers. Secondary skin lesions usually number less than 10, but patients with more than 100 such lesions have been reported.⁴

Spirochetes have been isolated from these lesions as well.⁸ Although patients may be systemically quite ill during this phase of illness, most of these symptoms will resolve without treatment, and the skin lesions typically fade over days to weeks. Months later, approximately 5% of untreated patients have recurrences of secondary lesions.

Borrelia Lymphocytoma

A rare early cutaneous manifestation of Lyme disease is borrelia lymphocytoma,⁹ a tumor-like violaceous swelling or nodule at the base of the earlobe or the nipple caused by a dense lymphocytic infiltrate of the dermis. This lesion occurs at the site of a tick bite, is usually solitary, and may be associated with regional lymphadenopathy. In the setting of fever, fatigue, and adenopathy, borrelia lymphocytoma can be confused with a lymphoma. Untreated, this lesion may linger for 6-12 months before it disappears spontaneously.

Acrodermatitis Chronica Atrophicans (ACA)

ACA is a late skin manifestation of Lyme disease which is more prevalent in Europe than the U.S..¹⁰ ACA is an indurated plaque at a site distal to erythema migrans (e.g. hand, forearm, or foot) occurring after hematogenous spread of *B. burgdorferi* from a primary skin lesion. Untreated, this inflammatory phase of ACA may persist for years, followed by an atrophic phase in which affected skin acquires the appearance of crumpled cigarette paper. This change may be coincident with the development of Lyme arthritis or neurologic sequelae. Skin biopsy reveals epidermal atrophy with thinning and hyperkeratosis, and a chronic dermal infiltrate. Antibiotics are effective treatment for ACA, but 10% of such lesions progress to a sclerotic morphea-like appearance.¹¹

Cardiac Manifestations

Lyme carditis occurs in roughly 8% of untreated patients within two to six weeks following infection, and may be the initial manifestation of Lyme disease.¹² Fluctuating degrees of atrioventricular block, including first-degree heart block and Mobitz type I block, are the most common features of carditis, but may progress to complete heart block requiring a temporary pacemaker. The cardiac conduction abnormalities of Lyme disease are usually brief, lasting days to weeks, and generally do not require permanent cardiac pacing. However, one recently-described patient had residual Mobitz Type I block 16 months after removal of a temporary pace-

maker for Lyme carditis.¹³

Less common cardiac manifestations have included arrhythmias (supraventricular tachycardia and premature ventricular contractions) and myopericarditis with transient cardiomegaly and left ventricular dysfunction. This latter problem may be mistaken for acute rheumatic fever when cutaneous and joint manifestations are also present. EKG changes in such patients may include diffuse T-wave flattening or inversion, and rarely ST segment depression. The diagnosis of Lyme disease should be considered in all cases of unexplained heart block, because it is treatable with antibiotics.

Neurologic Manifestation

Neurologic abnormalities, which occur in approximately 15% of untreated patients generally within two to eight weeks after disease onset, may include aseptic meningitis, cranial nerve palsies, peripheral radiculoneuritis, and peripheral neuropathy.¹⁴ Later neurologic sequelae, such as demyelinating conditions, cognitive impairment, and chronic fatigue occur less commonly and may not become evident until several years after acute infection.

The predominant symptoms of Lyme meningitis are severe headache and mild neck stiffness, which may fluctuate for weeks after a posterythema migrans latent period. The cerebrospinal fluid (CSF) typically has a lymphocytic pleocytosis (15-700 WBC), slightly elevated protein levels with oligoclonal bands, and normal glucose levels, and is easily mistaken for aseptic meningitis. A relatively normal CSF with a high opening pressure (greater than 200 mm) suggestive of pseudotumor cerebri (with or without papilledema) may be responsible for persistent, refractory headaches, especially among children with Lyme disease.¹⁵ Atypical cases of Lyme disease have included patients with purulent Lyme meningitis,¹⁶ and recurrent acute meningitis.¹⁷ Nearly one-half of patients with Lyme meningitis will have an associated mild encephalitis with concentration deficits, emotional lability, lethargy, or focal cerebral dysfunction.¹⁸ During this acute phase of illness, CT scanning of the head is normal, and electroencephalograms may show mild slowing with excess sharp-wave activity.

Neuropathy of the seventh cranial nerve (Bell's palsy) occurs in up to 10% of patients with untreated early disease, and may persist for weeks or months before complete resolution. Bell's palsy may be bilateral¹⁹ and is sometimes accompanied by pain around the ear or jaw.

Peripheral radiculoneuritis also may occur within the first weeks to months of illness. Radiculoneuritis is characterized by radicular pain or paresthesia of the extremities or thoracic dermatomes, and is associated with abnormal nerve-condition studies of affected nerve roots. Occasionally loss of muscle strength with diminished reflexes in the territory supplied by individual peripheral nerves may suggest mononeuritis multiplex. Several neurologic sequelae may occur in combination; for example,

meningitis with Bell's palsy is particularly common. Generally, IgM or IgG antibodies against *B. burgdorferi* are detectable in patients with peripheral radiculoneuritis or meningitis, particularly if the illness has been present for longer than four weeks.

Chronic neurologic symptoms have also been reported in Lyme disease. Although the frequency of such symptoms is unknown, chronic sequelae appear to be uncommon. Reported symptoms have included cognitive impairment, behavioral changes, seizures, ataxia, and chronic fatigue. Neuropsychiatric testing of these patients may reveal organic brain dysfunction, and MRI scanning of the brain may reveal demyelinating lesions, cerebral atrophy, or ischemic infarcts.²⁰ Neuronal destruction may result in a static encephalopathy which may be refractory to antibiotic therapy. Improved delineation of the spectrum of late neurologic sequelae of Lyme disease is of paramount importance if rational treatment decisions are to be made in the management of these patients.

Lyme Arthritis

Arthralgia and myalgia are common features of early Lyme disease, however, frank arthritis during erythema migrans is unusual. An interesting and diagnostically useful rheumatic symptom in early Lyme disease is temporomandibular joint pain, which is only rarely seen in other rheumatic disorders.²¹ Months to years after erythema migrans, 60% of untreated patients will develop joint manifestations ranging from migratory arthralgias to chronic destructive arthritis. The most common syndrome is an intermittent inflammatory arthritis of one or more large joints, particularly the knee; large joint effusions and Baker's cysts are common. Rarely, smaller peripheral joint involvement resembling seronegative rheumatoid arthritis may occur.²² Attacks of arthritis may last weeks to months and recur for several years; however, the prognosis of those with intermittent arthritis is generally good, with 10% to 20% spontaneously achieving long-term remission each year.²³ A minority of patients with arthritis will develop chronic, erosive disease, usually of a knee. Chronic arthritis is more prevalent among individuals with the class II HLA phenotypes DR3 and DR4.

Radiographs taken during an attack of arthritis are usually normal, with the exception of soft-tissue swelling. Additional radiographic changes later in the course of arthritis have included joint-space narrowing, subchondral sclerosis, osteophytes, enthesopathy, and erosions.²⁴ Synovial fluid analysis reveals a variable WBC count (500 to 100,000 cells; average 25,000 cells per cubic mm) with a predominance of neutrophils and rare eosinophils.²⁵

Protein levels may be modestly elevated (range 3.6 g/dl to 5.7 g/dl) with normal glucose and complement levels. Tests for serum antinuclear antibodies, rheumatoid factors, and VDRLs are generally negative. Anti-*B. burgdorferi* antibodies of the IgG class should be present in serum in patients with Lyme arthritis. Synovial biop-

sies are not helpful in diagnosis since the histopathology (villous hypertrophy, vascular proliferation, and mononuclear infiltration) is similar to that of rheumatoid arthritis, and the isolation of spirochetes from synovial tissue or from joint fluid is extremely difficult. Patients with long-standing arthritis with synovial proliferation and radiographic changes may be refractory to antibiotic therapy, and may require synovectomy.

The patient who complains of intermittent arthralgia and chronic fatigue, without objective findings, poses a particular diagnostic and therapeutic challenge. Although cases of seronegative Lyme disease have been reported,²⁶ physicians should hesitate in making a diagnosis of Lyme disease in such patients in the absence of objective evidence of inflammatory disease and anti-*B. burgdorferi* antibody titers. A search for other causes of arthralgia and fatigue, including depression, fibromyalgia, postviral neurasthenia, collagen vascular diseases, indolent infections, and neoplasms is indicated in such patients. Empiric antibiotic trials may be indicated in some patients with a clear history of exposure in an endemic area, a tick bite, and subjective symptoms, but in general, antibiotic treatment should be reserved for patients with objective findings on physical exam and positive serologic tests. Decision for treatment of such individuals should be made only after consultation by a clinician experienced in the treatment of Lyme disease and after properly informing the patient of the diagnostic uncertainty inherent when objective physical findings and positive serologies are lacking.

Ocular Manifestations

Ocular manifestations may occur in Lyme disease, and include cranial nerve palsies (sixth and seventh nerves), iritis, optic neuritis, panophthalmitis with loss of vision,²⁷ interstitial keratitis with potential corneal opacity,²⁸ and choroiditis with retinal detachment,²⁹ as in other spirochetal infections, high-dose systemic antibiotics are required when *B. burgdorferi* causes ocular symptoms.

Pregnancy

Adverse fetal outcomes due to maternal-fetal transmission of Lyme disease have been reported,³⁰⁻³² but a uniform pattern of congenital malformations has not been identified. Of equal importance, however, is that the majority of such pregnancies are normal.³¹ Adverse outcomes include fetal demise with abnormalities of the heart and great vessels,^{30,31} as well as autopsy reports of septal defects and coarctation of the aorta. If Lyme disease is contracted during the first trimester of pregnancy, coincident with cardiac organogenesis, an increased risk of fetal cardiac anomalies may be present. Other adverse outcomes, which occurred despite antibiotic therapy, have included syndactyly, cortical blindness, and fetal wastage.³¹

In a prospective study of abortuses in an area endemic for Lyme disease, four cases of fetal borreliosis were described with *B. burgdorferi* isolated from fetal liver.³³ This observation suggests that *B. burgdorferi* may be an

etiologic agent in fetal demise of uncertain cause. The risk to infants of asymptomatic women with positive serologies for Lyme disease has been explored through analysis of cord blood for anti-*B. burgdorferi* antibodies. No association was noted between the presence of anti-*B. burgdorferi* antibodies in cord blood and the occurrence of congenital malformations, although seropositive babies tended to have a lower birthweight by 150 grams. The development of these infants warrants further observation, especially since in another spirochetal infection, congenital syphilis, abnormalities are not always evident at birth.

Conclusion

In summary, Lyme disease usually begins during the summer months with erythema migrans and flu-like symptoms, followed weeks to months later by cardiac or neurologic complications in a minority of affected individuals. Arthritis occurs in many untreated patients weeks to years after disease onset. Early antibiotic therapy generally aborts the later manifestations of Lyme disease and aggressive antibiotic therapy is generally effective in eradication of infection during later stages of illness. Current clinical research efforts are being directed toward prevention of infection, improvement in methods of serologic diagnosis, further delineation of the clinical spectrum, and optimizing treatment of all stages of disease.

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Laboratory Analyses for Lyme Disease

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ABSTRACT—Numerous techniques are available for the laboratory diagnosis of Lyme disease. Assays for the detection of antibodies to *Borrelia burgdorferi* are the most practical means of confirming infection. False positive reactions can occur, but the more serious disadvantages are low sensitivity and lengthy processing time. Nonetheless, serologic tests are being improved and remain valuable research and diagnostic tools. Serologic test results for antibodies to *B. burgdorferi* should be considered along with clinical data and epidemiological information when evaluating a patient for Lyme disease.

LABORATORY analyses of serum specimens are important aids in the diagnosis of infectious diseases. They confirm clinical diagnoses. With increased public awareness of Lyme disease and the sometimes confusing clinical presentation of this malady, serologic testing for antibodies to the etiologic agent, *Borrelia burgdorferi*, has been relied on heavily by the medical community. Although analyses for antibodies have been improved, technical problems remain and there is difficulty with the interpretation of test results. False positive and false negative reactions occur. The purpose of this communication is to review the practical aspects of laboratory testing for Lyme disease and to comment on the advantages and disadvantages of the methods being used.

Procedures Available

When spirochetes were first isolated from the tick vector, *Ixodes dammini*,¹ indirect fluorescent antibody (IFA) staining methods were applied to determine if serum from patients with clinical manifestations of Lyme disease contained specific antibodies to this type of bacterium. Results verified the presence of total immunoglobulins and provided the first clue that a spirochete was indeed the causative agent. Shortly thereafter, polyvalent and class-specific IFA procedures were developed by persons in different laboratories to confirm *B. burgdorferi* infections.²⁻⁵ These methods are still being used in

laboratories that have low to moderate requests for analyses. In Connecticut and other areas where Lyme disease is highly endemic, the laborious IFA staining methods soon became impractical because large numbers of serum samples were being submitted and there were demands for rapid reporting of test results.

The development of enzyme-linked immunosorbent assays (ELISA) improved diagnostic testing for Lyme disease.⁵⁻⁹ Successful application of these automated procedures enabled laboratory personnel to meet numerous requests. Regardless of whether polyvalent or class-specific assays were used, there seemed to be greater sensitivity and less variability in ELISA compared with IFA methods. The more objective test results of ELISA were clearly advantageous. Different enzyme-substrate systems have been evaluated and are available to meet particular needs. In general, ELISA is preferred over IFA methods.

Immunoblotting techniques are being used along with ELISA to characterize immune responses and for diagnoses.¹⁰⁻¹⁶ Western blot analysis can verify reactivity of antibody to major surface or flagellar proteins of *B. burgdorferi*. For example, during the early stages of Lyme disease infection in humans, a polypeptide of an approximate molecular weight of 41 kilodaltons is recognized immunologically.^{10,11,14} As disease progresses to later stages, there is an expansion of antibody production to numerous proteins including an outer surface polypeptide (31 kilodaltons) that is specific for *B. burgdorferi*.^{10,11,13,16} Although these procedures are sensitive and have clarified patterns of immune response in patients who have Lyme disease, they are time-consuming, and in most clinical laboratories, are not performed routinely.

There are several commercial antibody test kits available for verifying *B. burgdorferi* infections. These include IFA and ELISA procedures for total immunoglobulins (Ig) or IgM and IgG antibody. Commercial test kits greatly simplify antibody detection methods, but the sensitivities and specificities of these assays vary considerably. During the development phase, each manufacturer relied on different collections of positive and nega-

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tive serum specimens for their evaluations, used different conjugated reagents, and, consequently, established dissimilar cutoff values for positive test results. The lack of standardization among companies parallels earlier events when investigators in different research laboratories first developed antibody detection procedures for Lyme disease.^{2,5,7,8} Interlaboratory differences in serologic test results have been reported¹⁷ and continue to be a problem.

There is a demand for antigen detection procedures because most assays for antibody have relatively low sensitivity. A reliable antigen detection test would complement the existing assays for antibodies. Highly sensitive methods are needed to verify the presence of *B. burgdorferi* in human blood, urine, cerebrospinal fluid, or skin tissues. *Borrelia burgdorferi* can be cultured in a liquid medium,¹⁸ but, in practice, this procedure is expensive and generally regarded as a low-yielding process. Silver-staining¹⁹ and FA staining techniques also have been used to locate *B. burgdorferi* in skin biopsy or tick-tissue preparations.^{1,3} Unfortunately, the time required to find a small number of spirochetes in human tissues by microscopic examination is often excessive. A modified ELISA has recently proved satisfactory for detecting *B. burgdorferi* in human and mouse urine specimens,²⁰ and with further development and evaluations, this system or a DNA probing technique may eventually be implemented as a routine diagnostic procedure. In short, the antigen detection procedures currently available have limited use as laboratory aids in confirming *B. burgdorferi* infections in patients.

Sensitivity of Antibody Tests

Three to four weeks after onset of erythema migrans, the best clinical marker for Lyme disease,²¹ IgM antibody usually rises to detectable levels.² Production of this immunoglobulin continues for about a month, when IgG antibody first appears. As titers of IgG antibody increase, production of IgM antibody normally declines or ceases.² Depending on the severity of infection and immunologic response, IgG antibody may persist at relatively high titers for months or years.^{11,22,23} Upon successful antibiotic treatment, IgG antibody titers may decline or remain elevated.

The sensitivities of IFA methods and ELISA are usually low during the initial three weeks of infection,^{12,23,24} and negative test results are common. In most instances, the performance of these assays improves dramatically when persons progress to the later stages of disease. Non-reactivity of serum samples is due to one or more of the following factors: early collection of blood samples before IgM antibody rises to a detectable level, curtailment or abortion of immune response resulting from antibiotic therapy,^{2,23} delayed immune response in persons,^{11,25} or low assay sensitivity caused by technological problems or the use of high cutoff levels for a positive result.

Efforts have been made to improve the sensitivity of antibody tests. Application of capture ELISA techniques for IgM antibody²⁶ has increased seropositivity rates for persons in the early stage of infection, but the extra time needed to perform this assay is a disadvantage. The purification or extraction of the most immunogenic proteins of *B. burgdorferi* has enabled researchers to test subunits of antigen in ELISA.^{10,13,14,27} Purified flagellin,¹⁴ coated to the polystyrene plates, has likewise increased the sensitivity of ELISA. However, further evaluations are needed before these methods are implemented commercially. Experimental application of these new procedures is limited to a small number of research laboratories.

Specificity of Antibody Tests

False positive reactions resulting from cross-reactivity can occur in tests for Lyme disease. For example, tick-borne relapsing fever spirochetes, *Borrelia hermsii*, are closely related to *B. burgdorferi*. Antibodies to *B. hermsii*, an agent that coexists with the Lyme disease spirochete in portions of Western United States,²⁸ strongly cross-react with *B. burgdorferi* in IFA staining and ELISA.^{7,29} Common antigens are shared among the *Borrelia* and even with the treponemes.³⁰ Serum samples from syphilitic patients react positively in tests for Lyme disease, but additional serologic analyses with the Venereal Disease Research Laboratory method or rapid reagin card test can usually separate these spirochetal infections.^{5,7} The occurrence of oral treponemes, such as *Treponema denticola*,³¹ and its association with periodontal disease in humans, needs further consideration. Antibodies produced to this bacterium may cross-react with *B. burgdorferi*. Serum antibodies to this or other treponemes may need to be removed by adsorption procedures before analyses for Lyme disease are performed. The use of subunit preparations of *B. burgdorferi*, lacking flagellin, has decreased the number of false positive reactions resulting from cross-reactivity of antibodies to *T. pallidum*.²⁷ Despite these cross-reactions, Lyme disease can usually be separated from other spirochetal infections clinically or epidemiologically.

Development of T-Cell Tests

During the early stage of *B. burgdorferi* infection, when serum antibody tests are most likely to be negative, there is vigorous T-cell activity.¹² This response usually precedes IgM antibody production. Utilizing limiting dilution analysis, investigators have been able to characterize T-cell response to *B. burgdorferi*. Therefore, a T-cell test could be used in laboratory diagnosis along with antibody tests. A T-cell assay would be particularly useful in instances when erythema migrans is lacking or develops atypically and when antibody tests fail to confirm *B. burgdorferi* infections in patients suspected of having Lyme disease.

Epidemiological Considerations

Clinical data and epidemiological information should be reviewed when interpreting serologic test results. Persons who live in highly endemic areas for Lyme disease are probably exposed to infected ticks throughout the warmer months. Mild or asymptomatic cases of Lyme disease have been reported,³² and prior exposure to *B. burgdorferi* may result in antibody production. These "residual" antibodies could complicate diagnosis if tests for Lyme disease are performed on serum from patients who present with skin manifestations or joint disorders that are unrelated but similar to those of *B. burgdorferi* infection. The number of persons with antibodies to *B. burgdorferi* and no history of Lyme disease seems to be low (less than 10%).³² Conversely, negative serologic results for persons who live in or enter tick-infested habitats, where Lyme disease occurs, should be interpreted with caution, particularly if clinical features are consistent with those of *B. burgdorferi* infection. In this instance, analysis of paired serum samples (i.e., two specimens collected at least four to six weeks apart) may be warranted.

Quantification of Antibody Titers

Although antibody titers for a given specimen can vary two-fold or sometimes four-fold on different days of testing, there is value in determining titration end points. A relatively low antibody titer near the cut-off level for a positive result may indicate a nonspecific reaction. A high-titered result is convincing evidence of prior or current *B. burgdorferi* infection. Therefore, when serologic test results are reported, some indication of quantitation (eg., either, as a dilution factor or an index of reactivity) should be given. Qualitative results (i.e., positive vs. negative) are less meaningful.

Monitoring antibody titers in patients that are untreated or given antibiotics can be misleading. As stated earlier, antibiotic therapy can interfere with immune response, and a decline in antibody titer may not necessarily indicate complete neutralization of *B. burgdorferi* in the host's tissues or organs. Further, antibiotics may effectively resolve spirochetal infection, but in some persons who no longer have signs or symptoms of Lyme disease, IgG antibodies may persist at relatively high titers for several weeks or months. It is unclear whether this antibody is protective in the event of reinfection via tick bites. Therefore, monitoring antibody titers repeatedly over short durations in particular seems to be of limited value unless a seroconversion can be documented. A change in status from negative to positive is confirmatory evidence of Lyme disease.

Testing Ticks for *B. burgdorferi*

When ticks are found attached to human skin, they are usually promptly removed and are sometimes submitted to a physician or public health official for identification

and analyses.^{33,34} Identification to species is important because *I. dammini* is the chief vector of *B. burgdorferi*; the nymphal stage of this tick appears to be more efficient in transmission than the adult. Males and females of American dog ticks (*Dermacentor variabilis*) also bite people but appear to have little or no significance as vectors of *B. burgdorferi*.³⁵ Utilizing murine monoclonal antibody (directed to a specific outer surface protein having a molecular weight of about 31 kilodaltons)³⁵⁻³⁷ and the appropriate conjugate, FA staining methods can be used to confirm the presence of *B. burgdorferi* in the tick's midgut tissues. However, the detection of this spirochete in a tick that was removed from a patient does not indicate that the bacterium was transmitted. Furthermore, failure to detect spirochetes in the tissues of a lightly infected tick and the reporting of an "uninfected" tick could be very misleading. One could easily miss these spirochetes in microscopic examinations of tick tissue preparations. Since the reliability of FA staining procedures to detect *B. burgdorferi* in ticks is unknown, this method is of questionable value as a diagnostic aid.

Conclusion

Serologic testing for antibodies to *B. burgdorferi* remains the most practical means of confirming Lyme disease. Advances made in producing more sensitive and specific assays should help physicians diagnose atypical cases. However, assay methods need to be standardized among laboratories and proficiency testing should be conducted to ensure quality of results.

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Treatment of Lyme Disease

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ABSTRACT—Lyme disease, a tick-transmitted spirochetal infection, can be divided into three stages that can overlap or occur alone. The goals of antibiotic therapy in stage one are to shorten the duration of early disease and to prevent the development of later stages of the illness. This can usually be accomplished with oral antibiotic therapy. Later stages of the illness are frequently more difficult to treat, requiring prolonged oral or intravenous antibiotic therapy.

Introduction

LYME disease is a multisystem disorder recognized in 1975 in patients living near Lyme, Connecticut.¹ Lyme disease is caused by a spirochete, *Borrelia burgdorferi*. This organism is transmitted primarily by ticks of the *Ixodes ricinus* complex, including *Ixodes dammini*. Lyme disease is now the most commonly reported tick-transmitted illness in the United States.²

Lyme disease can be divided into three stages that can overlap or occur alone. As in other spirochetal infections, antibiotic therapy is most effective early in the illness. The diagnosis of Lyme disease depends on a history of potential exposure to ticks in an endemic area, especially during the spring and summer, recognition of characteristic clinical features, and the use of Lyme disease-specific serologic testing, which is most useful during later stages of the illness.

Stage One (Early Disease)

Approximately 30% of individuals remember a tick bite several days to one month before they develop Lyme disease. Erythema migrans (EM) is a red macule that may develop at the site of the bite. When present in its typical form it is diagnostic. The rash often expands over several days to greater than 10 centimeters in diameter. If untreated, the rash usually fades within one to four weeks, although occasionally it persists for months. During this period, when Lyme disease is most successfully treated, the organism is thought to disseminate hematogenously. This may explain the presence in some patients of secondary annular skin lesions. Hematogenous dis-

semination of *B. burgdorferi* may also explain the constitutional symptoms, which are sometimes, but not always, seen during this stage.³

Treatment of Stage One

The goals of antibiotic therapy at the onset of Lyme disease are to shorten the duration of EM and associated symptoms and to prevent the development of later stages of the illness. During stage one, the disease can be treated effectively in approximately 90% of patients.⁴

The drug of choice in nonpregnant women, adults, and children with permanent dentition is an oral tetracycline, either tetracycline 250-500 mg four times daily or doxycycline 50-100 mg twice daily given for 10 to 21 days.⁴ The appropriate dosage and duration of treatment depends on the severity of disease at onset. Severe disease at onset is more likely to be associated with late complications than mild disease at onset.⁵ In general, since antibiotic therapy is most effective early in the illness, it is probably appropriate to treat most patients with more than mild illness at onset for a full three-week course of antibiotic therapy.

Phenoxymethyl penicillin 250-500 mg four times daily or amoxicillin 250-500 mg four times daily given for 10 to 21 days are also effective therapy for stage one Lyme disease.⁴ Phenoxymethyl penicillin is the drug of choice in pregnant women, lactating women, and children. Since an association between the onset of this infection during pregnancy and fetal malformations has been suggested,⁶ and since transplacental infection is postulated to occur very soon after disease onset, it is appropriate to treat pregnant women in whom Lyme disease is suspected with a lower threshold than other individuals. It has been suggested that intravenous penicillin be used in some pregnant women with relatively severe symptoms in stage one Lyme disease although the need for parenteral therapy in this setting is unproven.⁷ Children with deciduous teeth should receive phenoxymethyl penicillin 50 mg per kg per day (not less than one gram per day or more than two grams per day).

For adults allergic to tetracyclines or penicillins, erythromycin 250-500 mg four times daily for 10 to 21 days is a slightly less effective alternative.⁴ In children allergic to

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penicillin, erythromycin 30 mg per kg per day in divided doses for 10 to 21 days can be used.

Stage Two and Three (Late Disease)

Neurologic Disease

Weeks to months after the tick bite, about 15% of patients develop neurologic abnormalities. These include meningitis (associated with a lymphocytic pleocytosis), encephalitis, cranial neuropathy (Bell's palsy may be the only manifestation of Lyme disease), peripheral radiculoneuropathies, or myelitis.⁸ In untreated patients, neurologic abnormalities usually resolve completely within months, although chronic neurologic disease is increasingly recognized. Patients with late neurologic illness have been reported to have neuropsychiatric symptoms, focal disease of the central nervous system, or a fatigue syndrome.⁹

Treatment of Neurologic Disease

In patients with mild disease (for example Bell's palsy alone), tetracycline 250-500 mg four times daily for 10 to 21 days is effective.¹⁰ For individuals with frank meningitis, spinal fluid pleocytosis, and cranial or peripheral neuropathies, intravenous penicillin G 20 million units daily in divided doses for 10 to 14 days is usually effective.¹¹ Ceftriaxone 2 grams daily for 14 days is an alternative.¹² In one patient, chloramphenicol 1 gram intravenously every six hours for 10 days was effective following unsuccessful intravenous penicillin therapy.¹³ Patients with stage three neurologic complications of Lyme disease including neuropsychiatric disease, focal central nervous system disease, and fatigue syndromes, have been treated with intravenous penicillin G in the regimens suggested for serious stage two neurologic disease with variable success.⁹

Cardiac Disease

Less than 5% of patients develop cardiac involvement within several weeks after the onset of Lyme disease. In one series, 18 of 20 patients with cardiac disease had fluctuating degrees of atrioventricular block; eight of them developed complete heart block which was more likely to occur when the PR interval was longer than 0.30 seconds. Thirteen of these 20 patients had acute myopericarditis. These patients did not have valvular heart disease. The duration of Lyme carditis is usually brief (several days to several weeks), but recurrences are possible.¹⁴ Patients usually recover completely, although a cardiac death from Lyme disease has been reported.¹⁵

Treatment of Cardiac Disease

In patients with minor cardiac involvement (first degree atrioventricular block but PR interval less than 0.30 seconds) and no other significant symptoms, therapy with tetracycline as described for stage one disease is effective. Such patients should restrict their activity, however, and be monitored closely. Patients with Lyme carditis should probably receive aspirin 325 mg — six to 12 tablets daily (or an equivalent nonsteroidal anti-inflammatory drug [NSAID] in therapeutic dose) in

addition to antibiotic therapy. Patients with more severe manifestations of Lyme carditis (including first degree atrioventricular block with PR interval greater than 0.30 seconds) should be hospitalized with cardiac monitoring and treated with intravenous penicillin or ceftriaxone as described for serious neurologic disease.¹⁶ Some of these patients will have complete heart block requiring temporary transvenous cardiac pacemaker insertion, usually for less than one week.¹⁴ Persistent conduction system abnormalities requiring permanent pacemaker insertion are unusual but have occurred.

Arthritis

Within several days to weeks after disease onset, about 20% of patients develop arthralgias. These are typically brief episodes of migratory joint, periarticular, and musculoskeletal pain, but patients may continue to have attacks of arthralgias for up to six years without developing objective joint abnormalities. In addition to arthralgias, within days to years following untreated EM, about 50% of patients develop frank arthritis occurring as single or intermittent attacks of joint swelling lasting from several days up to one year. About 10% of patients with Lyme disease develop chronic arthritis which can be associated with permanent joint destruction.⁵

Treatment of Arthritis

Several oral regimens are successful in treating Lyme arthritis in approximately 50% of patients. In adults these include doxycycline 100 mg twice daily given for 30 days and amoxicillin 500 mg three times daily with probenecid 500 mg three times daily for 30 days.¹⁷

Children should receive phenoxymethyl penicillin 50 mg per kg per day (not less than one gram per day but not more than two grams per day) in four doses for 30 days.¹⁸

Penicillin G 20 million units intravenously daily in divided doses for 14 to 21 days¹⁹ or ceftriaxone two grams intravenously daily for 14 to 21 days are effective in approximately 75% of patients with established Lyme arthritis.¹² Children should receive penicillin G 250,000 units per kg per day intravenously in divided doses every four hours for 14 to 21 days.

Treatment Problems

Early Disease

Most patients treated at disease onset can be treated effectively with oral antibiotic therapy. Occasional patients with severe disease at onset may require parenteral therapy. Whether patients exposed to Lyme disease during pregnancy with constitutional symptoms require parenteral therapy is unknown. The greatest challenge in the treatment of early Lyme disease, however, is the recognition of this infection in a diverse group of patients, not all of whom have EM, and many of whom have mild or nonspecific constitutional symptoms. Serologic testing provides only limited help in identifying individuals with early Lyme disease.²⁰

Late Disease

Not all patients with neurologic manifestations or

with arthritis respond to oral or intravenous antibiotic therapy,¹⁹ and in many of these individuals, retreatment may be necessary. Retreatment is also appropriate in individuals who relapse, for example, with recurrent arthritis.

In adults with chronic knee arthritis who do not respond to antibiotic therapy, arthroscopic synovectomy has been successful in some patients. Other patients with arthritis require management with NSAID therapy. Intra-articular corticosteroid injection can improve function but has been correlated with unsuccessful subsequent antibiotic therapy.²¹ Ultimately, in most patients, Lyme arthritis can be arrested without significant joint destruction.⁵

Among patients with neurologic manifestations of Lyme disease, most cases can be successfully treated with currently available treatment regimens.¹¹ Late in the illness, cases refractory to antibiotic therapy may be encountered.⁹

Current research efforts are being directed toward improving the therapy of early disease with antibiotic programs that further reduce the risk for developing later stages of the disease. Prospective studies to better define the risk to the fetus in a mother exposed to Lyme disease as well as studies to optimize the treatment of chronic arthritis and neurologic disease are also needed.

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A Prospective Study of Tick Bites in an Endemic Area for Lyme Disease

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LYME disease, which is caused by *Borrelia burgdorferi*^{1,2} is transmitted primarily by *Ixodes dammini* or related ixodid ticks.³ In field studies in Connecticut, the spirochetal pathogen has been found in 10%-35% of these ticks;³⁻⁵ on Shelter Island, New York, >50% of ticks have been infected with this organism.⁶ After an incubation period of three to 32 days, patients bitten by the tick may develop a typical skin lesion, erythema migrans, at the site of the bite; this lesion may be accompanied by flu-like or meningitis-like symptoms.⁷ If untreated, many of these patients subsequently develop neurological, cardiac, or joint abnormalities.⁸ In a minority of patients, the early stages of the disease are asymptomatic, and the illness presents with the more-debilitating later stages.⁹ In others, the infection seems to remain subclinical.^{9,10} Early diagnosis and treatment are important, because the results of antibiotic therapy are better when given early in the illness.¹¹

Public awareness of this disease has increased in endemic areas. In such areas, people commonly find ticks attached to themselves multiple times during each summer. Because infection rates in ticks are high, primary care physicians are then faced with the dilemma of whether to treat such patients immediately or to wait and treat them only if the symptoms of Lyme disease develop. Currently, the risk-benefit ratio of disease prevention versus adverse effects of unnecessary antimicrobial therapy is unknown.

To address this question, we conducted a double-blind, placebo-controlled trial of penicillin prophylaxis in patients bitten by *I. dammini* ticks in an endemic area for Lyme disease. We found that the risk of acquiring

Lyme disease from recognized tick bites was less than one would expect from the infection rate in ticks.

Subjects and Methods

Study plan and population. From May to November 1986, in collaboration with the Middlesex Family Practice Residency Program, 45 physicians affiliated with the Middlesex Memorial Hospital in Middletown, Connecticut, invited patients with *I. dammini* tick bites to participate in a double-blind study of penicillin versus placebo for preventing Lyme disease. Patients were asked to bring the tick, attached or not, for identification and analysis. Patients were excluded if they had noticed the tick bite >72 hours previously, were already taking oral antibiotics, were pregnant, were less than five years old, were allergic to penicillin, or were already symptomatic with Lyme disease. One patient who had been treated for erythema migrans two years previously was included when his titers of antibody to *B. burgdorferi* were shown to be negative at the time of entry into the study.

Each participant completed a standardized questionnaire. Participants were asked whether they had past or current symptoms of Lyme disease, including skin rash, myalgias, summer flu-like symptoms, headache, Bell's palsy, myocarditis, or joint effusions. In addition, a blood sample was drawn for determining antibody titers to *B. burgdorferi*. The patient was then given a numbered vial containing 40 pills and was told to take one tablet four times a day for 10 days. These vials, which had been filled and numbered by personnel in the Middlesex Hospital Pharmacy, contained either tablets of 250 mg of phenoxymethyl penicillin or tablets of 333 mg of lactose (Consolidated Midland, Brewster, NY) that had been made to look exactly like the antibiotic. Neither the physician nor the patient knew which preparation he or she had received.

The patients were told to report to their physician immediately if they developed symptoms of Lyme disease. Regardless, they were asked to return three weeks and six months later to provide blood samples for determining antibody titers to *B. burgdorferi*. At the conclusion of the study, six to 12 months after their

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initial presentation, we again questioned patients by mail regarding any possible symptoms of the illness. Patients with symptoms or with elevated antibody titers were interviewed by the study physician (C.M.C.) and by their personal physician, and their records were consulted if necessary. Twelve patients who were initially enrolled in the study were excluded from the final analysis because they did not complete the study protocol.

Laboratory studies. When an *I. dammini* tick was still attached to the patient, the tick was removed with forceps, the body was slit with a scalpel, and the contents were smeared onto a slide. The slide was sent on the same day to the Middlesex Memorial Hospital laboratory, where it was fixed with cold acetone and frozen at -30C. Later, the slides were examined by direct immunofluorescence at Yale University, as previously described.² All serum samples were also taken to Middlesex Memorial Hospital, where they were frozen at -30C. After all of the samples had been collected, antibody titers to *B. burgdorferi* were determined at the Yale University School of Medicine by using an ELISA, as outlined before.¹² A positive serological response to *B. burgdorferi* was defined as an IgM or IgG value >200 units or a fourfold increase in the antibody titer between acute and convalescent sera.

Results

Infection rates in ticks. Of the 56 patients who completed the study protocol, 16 (29%) had an *I. dammini* tick removed by the study physicians, 32 (57%) brought this type of tick to the physicians' offices, and 8 (14%) gave a history of a bite by a tiny tick within the previous 72 hours. Of the 48 ticks brought, attached or unattached, to physicians' offices, 27 were already dessicated, and no fluid was obtained for smearing on the slide. Of the remaining 21 ticks, six (29%), three each from patients given either penicillin or placebo, were positive for *B. burgdorferi*.

Clinical outcome. Of the 56 patients, 27 were treated with penicillin, and 29 received placebo. Their mean age was 37 years (range, 5-85 years); 36 were female and 20 male. Of the 29 patients in the placebo group, one (3%) developed erythema migrans, headache, malaise, and fatigue 14 days after the tick bite (Table 1). In her case, the tick was not suitable for study, and it was not known whether it was infected. She was treated with 100 mg of doxycycline orally twice a day for 10 days and had complete resolution of symptoms within that time. Serological results for antibody to *B. burgdorferi* remained negative, and she had no recurrent symptoms of the illness.

Of the 27 patients in the penicillin group, none experienced symptoms of Lyme disease (Table 1). One (4%) patient, however, developed a pruritic, erythematous maculopapular rash over the arms, neck, and face after five days of penicillin treatment. She still completed the 10-day course of antibiotic therapy. Twelve additional patients who enrolled in the study, five of whom received penicillin, were excluded because they did not return for follow-up blood samples. None of them developed clinical symptoms of Lyme disease.

Serological findings. Forty-four of the 56 patients, 24 in the placebo group and 20 in the penicillin group, had blood samples drawn at initial presentation, three weeks later, and six months after the tick bite. The remaining 12 patients, five in the placebo group and seven in the penicillin group, gave two serum samples. None of the 56 patients had either symptomatic or asymptomatic seroconversion (Table 1). Five patients, two of whom received penicillin, however, had positive IgG antibody titers to *B. burgdorferi* in the first sample (range, 800-3200 units); these titers remained elevated three weeks and six months

Table 1
Clinical and serological outcome of patients with tick bites, according to treatment.

Outcome	No. (%) of patients receiving		
	Placebo (n = 29)	Penicillin (n = 27)	Total (n = 56)
Clinical			
Cases of Lyme disease	1 (3)	0	1 (2)
Adverse reactions to medication	0	1 (4)	1 (2)
Serological			
Positive titers of <i>B. burgdorferi</i> antibody at entry	3 (10)	2 (7)	5 (9)
Seroconversion during study	0	0	0

later. Although none of the patients had been diagnosed as having Lyme disease, one had had a rash on the arm and had had pain and swelling of the elbow two years previously, and another had had facial "cellulitis" treated with dicloxicillin several months before the study. The remaining three patients (5%) had had no previous symptoms that could be attributed to Lyme disease.

Discussion

In this study, we identified patients bitten by *I. dammini* ticks and treated them with either penicillin or placebo in an effort to prevent Lyme disease. In ~30% of cases, the tick was removed by the study physician and was examined for spirochetes. More commonly, the patient had already removed the tick at home and brought it to the physician's office. This allowed identification of the tick by the physician, but the tick was often too damaged or dessicated to be examined for spirochetes. Finally, eight patients were included in the study who did not save the implicated tick but said that they had been bitten by a tiny tick within the past 72 hours. Only two ticks in Connecticut bite humans, the American dog tick *Dermacentor variabilis* and the deer tick *I. dammini*, and the latter is considerably smaller. Of the 21 ticks that we were able to examine, six (29%) were infected with *B. burgdorferi*. This result is in agreement with the percentages of infected ticks found in field studies in southeastern Connecticut.³⁻⁵

Despite the finding that one in three ticks were carriers of the spirochete, only one in 29 patients in the placebo

group developed symptoms of Lyme disease. In a similar study in West Germany, 47 (17%) of 272 *Ixodes ricinus* ticks removed from children were found to be infected with *B. burgdorferi*, but only one child developed symptomatic Lyme disease.¹³ Why is the frequency of infection in patients so much less than the frequency of infected ticks? Perhaps some strains of *B. burgdorferi* are not infectious, too few spirochetes are transmitted, or some people are not susceptible to the infection. Probably a major reason is that *I. dammini* often feeds upon its host for many hours before transmitting the organism. In a study of experimental transmission, *B. burgdorferi* was cultured from one of 14 hamsters fed upon for one day, five of 14 exposed for two days, and 13 of 14 exposed for three or more days.¹⁴ We initially attempted to estimate the duration of tick attachment in our patients by history and by the degree of tick engorgement. Patients usually did not know how long the ticks had been attached, however, and physicians had difficulty assessing engorgement in tiny nymphal *I. dammini*.

Tetracycline has been recommended as the treatment of choice for early Lyme disease.¹¹ In this study, however, we chose penicillin as a prophylactic agent, because it is also effective in treating early Lyme disease,^{11,15} it can be given to persons in all age-groups, and it does not cause photosensitive rashes. Except for one patient who developed an allergic rash, penicillin was well tolerated by the study participants.

The major concern with delaying treatment until symptoms develop is the patient who remains asymptomatic early in the disease but then develops the more-debilitating and difficult-to-treat later manifestations of the illness. In the prevalence surveys, subclinical infection was noted in 6.8% of Fire Island residents¹⁰ and in 8% of Great Island residents,⁹ and in the prospective parts of these studies, a few patients had asymptomatic seroconversion. In this study, five (9%) asymptomatic individuals had elevated antibody titers to *B. burgdorferi* upon entry into the study, but no one had asymptomatic seroconversion. The risk of subclinical infection in these patients is unclear, but only one patient with asymptomatic infection in the previous study⁹ is known to have subsequently developed a late manifestation of the disease, acrodermatitis chronica atrophicans.

In this study of an endemic area that had a 30% infection rate in ticks, the risk-benefit ratio of disease prevention versus penicillin reaction appeared to be nearly equal. One of the 29 patients given placebo developed early Lyme disease, and one of the 27 given penicillin had an allergic reaction. These numbers are too small, however, to show significant differences between the groups. On the basis of a power analysis of a 3% infection rate in the placebo group and no infections in those treated with antibiotics, 258 patients would be required in each group to be 80% certain of showing a significant difference between the groups at the .05 level. It should be emphasized that the risk-benefit ratio observed here may be different in a larger study, in an area where more ticks are infected, or when other antibiotics are used.

The most important measures for preventing Lyme

disease are wearing protective clothing in tick-infested areas during the summer, using insect repellants, showering after exposures in such areas, and checking for attached ticks. The current study was too small to definitively answer the question of whether prophylactic antibiotics for tick bites is an advisable policy, and the decision of whether to treat remains a clinical judgment in the individual case. The observations made here, however, suggest that the risk of acquiring Lyme disease from a recognized tick bite is less than one would expect from the infection rate in ticks and may not be much greater than the risk of an adverse reaction to antibiotic therapy.

Informed consent was obtained from the subjects.

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Lyme Disease and Pregnancy

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AS our understanding of Lyme disease has grown, there has been increasing concern about its similarities to syphilis and the possibility of transplacental transmission of *Borrelia burgdorferi* (the spirochete that causes Lyme disease) from a pregnant woman to her fetus. The purpose of this communication is to review the published information in this area, to help physicians respond to questions from patients, and to describe the procedure for reporting Lyme disease cases.

Literature Review

The published literature on Lyme disease during pregnancy is limited. Several case reports suggest that Lyme disease can be transmitted transplacentally.¹⁻³ However, two small follow-up studies of pregnant women with Lyme disease, most of whom were treated with antibiotics, failed to demonstrate a definite link between Lyme disease during pregnancy and adverse fetal outcomes.^{5,6} Similarly a pilot study of two cohorts of babies, one born in a hospital located in a Lyme disease endemic area and the other born in a nonendemic area, found no association between congenital malformations and the presence of detectable IgG-specific antibodies to *B. burgdorferi*.⁶

Case Reports

In 1985 Schlesinger et al¹ reported the first case of

transplacental transmission of Lyme disease. They identified spirochetes morphologically compatible with *B. burgdorferi* in multiple organs of an infant who had died of complications of congenital heart disease shortly after premature delivery. The mother had developed erythema migrans (EM) in the first trimester of pregnancy but was never treated. Although spirochetes were seen in spleen, kidney, and bone marrow, they were not seen in heart tissue. Therefore, a definite link between this infant's heart disease and congenital Lyme disease could not be established.

Similarly, Weber et al described postmortem detection of *B. burgdorferi* in the brain and liver of a child who had died at 24 hours of age from the consequences of perinatal brain damage.² The child's mother had been treated during the first trimester of pregnancy for EM with a seven day course of low dose oral penicillin (current recommendation is for 10 days to three weeks). McDonald et al observed *B. burgdorferi* in multiple organs including the myocardium of a stillborn term infant whose mother had not sought medical attention for EM in the first trimester of pregnancy.³ Although there was "no significant" tissue inflammation, the authors felt the infant had died of "overwhelming spirochetosis."

Follow-up Studies

Two follow-up studies of women with early Lyme disease during pregnancy have both been conducted by the Centers for Disease Control (CDC). In the first, Markowitz et al reported on 19 pregnancies identified before knowledge of fetal outcome.⁴ Thirteen women had received antibiotics. Five of the 19 women had adverse outcomes, three of whom had received antibiotic therapy. Adverse outcomes included prematurity, cortical blindness, intrauterine fetal death, syndactyly, and rash in the newborn. Unlike the case reports noted above,¹⁻³ Lyme disease could not be directly implicated in any of these outcomes. Furthermore, there was no apparent pattern to the abnormalities, and there did not appear to be any relation to the trimester of infection or

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Reprint requests: State of Connecticut Department of Health Services, Epidemiology Program, 150 Washington St., Hartford, CT 06106 (Dr. Cartter).

to whether or not the mother had received antibiotic therapy.

In the second study conducted by the CDC, Ciesielski et al⁵ reported on 17 women who acquired Lyme disease while pregnant, and were followed prospectively. All of these women received antibiotic treatment and 15 delivered normal infants with no evidence of *B. burgdorferi* infection (negative cord blood IgM). One woman had a spontaneous abortion at 13 weeks, having acquired Lyme disease nine weeks earlier. However, cultures and stains of fetal tissues could not document *B. burgdorferi* as the etiology of the abortion. Another woman who acquired Lyme disease at seven weeks, delivered a child with syndactyly.

Finally, Williams and coworkers reported on a pilot study in which they examined 421 cord blood sera and found no association between congenital malformations and the presence of detectable IgG-specific antibody to *B. burgdorferi*.⁶ Although the babies with detectable antibodies tended to be of lower birthweight, to be small for gestational age, and to have had some degree of neonatal jaundice, these trends were not statistically significant.

Comments on the Literature

Even if one assumes that all of the adverse pregnancy outcomes described above were due to maternal Lyme disease (and this is probably not the case), these findings suggest that early Lyme disease during pregnancy, when properly diagnosed and treated most often results in a normal outcome. Additional research is needed to define the exact risk of transplacental transmission of Lyme disease, the clinical consequences of such transmission, and the appropriate management of these cases.

Treatment Issues

Pregnant women with Lyme disease should be aggressively treated with a full course of antibiotics, according to the stage of their disease.⁵ One question that is often

asked is whether pregnant women with early Lyme disease, including constitutional flu-like symptoms and EM, should be treated with parenteral antibiotics. Currently, there are no data available that establish the need for parenteral antibiotics for early Lyme disease during pregnancy. Another question that is frequently asked is whether pregnant women and other people with documented tick bites by *Ixodes damini* should be treated with prophylactic antibiotics. At present, there is no evidence to support the practice of treating all such bites empirically versus treating only when early symptoms develop.⁷

Case Reporting

Lyme disease is a reportable disease in Connecticut. Health care providers should report cases using the PD23 form, which is available from the Epidemiology Program office. If a pregnant woman is diagnosed as having Lyme disease, please notify the Epidemiology Program by telephone at (203) 566-5058.

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Ecology of Lyme Disease

JOHN F. ANDERSON, PH.D.

ABSTRACT—*Borrelia burgdorferi* is transmitted from wild animals to humans by the bite of *Ixodes dammini*. This tick is common in many areas of southern Connecticut where it parasitizes three different host animals during its two-year life cycle. Larval and nymphal ticks have parasitized 31 different species of mammals and 49 species of birds. White-tailed deer (*Odocoileus virginianus*) appear to be crucial hosts for adult ticks. All three feeding stages of the tick parasitize humans, though most infections are acquired from feeding nymphs in May through early July. Reservoir hosts for the spirochete include rodents, other mammals, and even birds. White-footed mice (*Peromyscus leucopus*) are particularly important reservoirs, and in parts of southern Connecticut where Lyme disease is prevalent in humans, borreliæ are universally present during the summer in these mice. Prevalence of infected ticks has ranged from 10-35%. Isolates of *B. burgdorferi* from humans, rodents, and *I. dammini* are usually indistinguishable, but strains of *B. burgdorferi* with different major proteins have been identified.

LYME disease is caused by a spirochete, *Borrelia burgdorferi*,¹⁻⁴ that is transmitted from animals to humans in northeastern and midwestern states by the bite of a tick, *Ixodes dammini*. This illness is becoming prevalent in many Connecticut communities,⁵⁻⁷ primarily because of rising numbers of ticks⁸⁻¹² infected with spirochetes.^{4,13-16} Humans encounter ticks in woodlands, in grassy and shrub-like areas along beaches, in parks, in yards around homes,¹⁷ and even inside houses after domestic animals and humans have inadvertently carried crawling ticks inside. This narrative focuses on the ecology of the tick vector in Connecticut, the vertebrate reservoir hosts for the spirochete, seasonal transmission of spirochetes between ticks and animals, and the spirochetel variants from the original B31 strain of *B. burgdorferi* that have been isolated from ticks and wildlife.

Tick Biology

Geographic distribution—The emergence of Lyme disease coincides with the relatively recent increase in

numbers of *I. dammini* in southern Connecticut (Fig. 1).⁹ Ticks are particularly numerous in many areas of New London and Middlesex Counties and in some parts of New Haven County. Their numbers have increased in recent years in Fairfield County,¹⁸ and they are well-established in the southern-most areas of Hartford and Tolland Counties. Few ticks have been collected in Litchfield County, but reports of increasing numbers in adjacent Dutchess County, New York, may be a harbinger of change for northwestern Connecticut.^{19,20} Dense populations have not yet been documented in northeastern Connecticut.

Seasonal history—During its putative two-year life cycle, *I. dammini* passes through four life stages—egg, larva, nymph, and adult.^{9,11,21-23} Engorged females lay their eggs in a single cluster on the ground in the spring. After hatching, larvae seek hosts primarily in midsummer to early fall (July-September) and feed for three to seven days.²¹ Upon repletion, larvae fall to the ground where they molt into nymphs. This second feeding stage most frequently parasitizes vertebrates in the following spring and early summer (May through early July), though nymphs have been found on hosts as early as March and as late as November. Nymphs usually become fully-fed in four to seven days and molt into adults on the ground.²¹ Adult females most actively seek hosts in the fall and in early spring of the following year, though they also are active on warm days in winter. Adult males feed sparingly and mate with feeding females. Females complete feeding on a host in eight to 11 days.²¹

Host animals—Larval and nymphal ticks feed on a wide range of small-, medium-, and large-sized animals, whereas adult ticks parasitize relatively fewer hosts. Subadult ticks have parasitized at least 31 different species of mammals and 49 species of birds.^{8-13,24} They may eventually be found to feed on almost every species of land mammal, with the possible exception of bats, and every species of ground-inhabiting bird in Connecticut. Some species, such as the white-footed mouse (*Peromyscus leucopus*), are more important than others. However, gray squirrels (*Sciurus carolinensis*), short-tailed shrews (*Blarina brevicauda*), woodland jumping mice (*Napaeozapus insignis*), raccoons (*Procyon lotor*), and even white-

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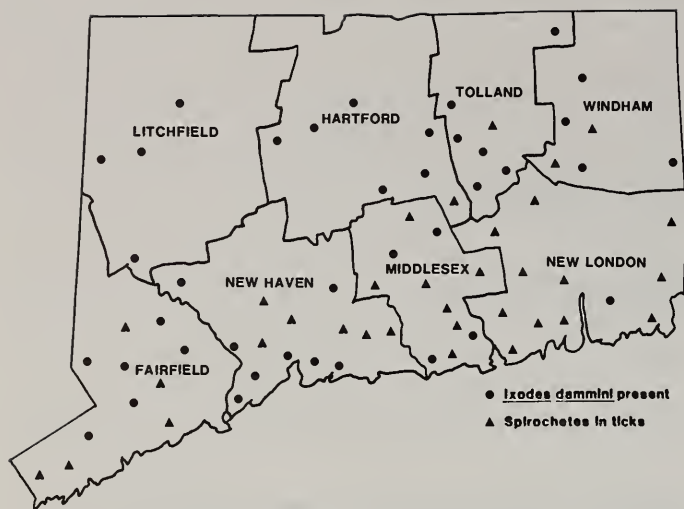


Figure 1

Geographical distribution of *Ixodes dammini* in Connecticut.^{9,48}

tailed deer (*Odocoileus virginianus*) also may be parasitized by relatively large numbers of larvae.^{11,24,25} In addition to white-footed mice, nymphs feed extensively on eastern chipmunks (*Tamias striatus*), gray squirrels, and raccoons. Less is known about the importance of birds as hosts, but relatively large numbers of subadult ticks have been observed on American robins (*Turdus migratorius*), swamp sparrows (*Melospiza georgiana*), and common yellowthroats (*Geothlypis trichas*).¹³ Birds are a natural means for dispersing engorged ticks into new areas, and like mammals, also serve to replenish local tick populations with engorged ticks.

Adult ticks have been collected from 13 species of medium- and large-sized mammals;^{8,10,23,24} they are not known to feed on birds and only rarely parasitize rodents. White-tailed deer appear to be crucial for maintaining tick populations.^{9,23,24,26-31} It is noteworthy that *I. dammini* became abundant only in the late 1960s and early 1970s, after deer became relatively abundant (the dozen or so deer reported in 1896 by the Connecticut Commissioners of Fisheries and Game contrast with the 31,000 deer estimated to be present in the winter of 1987-88 by the Connecticut Department of Environmental Protection).

All three motile stages of the tick parasitize humans. While most persons will be parasitized by a single tick at any one time, multiple bites can occur. For example, a woman, who previously had been diagnosed with Lyme disease, sent to the Experiment Station a piece of cellophane tape with five attached juvenile ticks and wrote that she had removed 15 others from her body after a walk in the woods in Guilford in 1985.³² Humans are accidental hosts, and unlike wild animals, are not significant in helping to maintain tick populations.

Animal Reservoirs for Spirochetes

Isolation from animals—*Borrelia burgdorferi* was initially isolated from white-footed mice captured in Connecticut and Long Island.^{14,33} Subsequently these rodents

were shown to be universally infected during summer and fall in southeastern Connecticut³⁴ and probably to retain spirochetes throughout their lives.³⁵⁻³⁸ The competency of white-footed mice to infect *I. dammini* further identifies these wild rodents as prime reservoirs.³⁶ The prevalence of infected ticks of 10-35% is, in part, a result of relatively large numbers of larvae feeding on infected white-footed mice.^{4,13-15}

Other wild animals also are infected with *B. burgdorferi* and can serve to infect feeding ticks. Isolates have been obtained from a raccoon, eastern chipmunks, meadow voles (*Microtus pennsylvanicus*), a woodland jumping mouse, cottontail rabbits (*Sylvilagus floridanus*), and a veery (*Catharus fuscescens*) songbird.^{14,24,29,32,34,39,40} There have been conflicting reports of white-tail deer as reservoirs.^{25,41} Additionally, borreliae have been isolated from humans with diagnosed Lyme disease^{3,4} and detected in clinically ill dogs, cows, and horses.⁴²⁻⁴⁶

Serosurveys of mammals—Serologic surveys of wild and domestic mammals further confirm the extensive exposure of animals to borreliae in Connecticut. Significant titers of antibody to *B. burgdorferi* were recorded for 68% of lame dogs from southern Connecticut.⁴⁶ Antibodies to this bacterium also have been detected in white-tailed deer (< 28%), horses (14%), white-footed mice (< 29%), raccoons (< 23%), eastern chipmunks (17%), gray squirrels (50%), and Virginia opossums (17%).^{15,16,47-50}

Seasonal Transmission of Spirochetes

The transmission of spirochetes between ticks and their hosts is enhanced by the seasonal appearance of nymphs before the larvae. While animals may become infected during any season, most acquire spirochetes in May through July following bites of infected nymphs. Larvae hatch from eggs in the summer and acquire borreliae when they feed in July through September on white-footed mice and other hosts, which, earlier in the year, had been parasitized by infected nymphs. Adult female ticks also are competent to vector borreliae to their hosts in the fall, on warm days in winter, and in spring, and occasionally they pass spirochetes directly to their offspring.^{51,52}

Variation Among Spirochetes

Isolates of *B. burgdorferi* from humans, rodents, a raccoon, and *I. dammini* in northeastern United States are often indistinguishable from one another and from the B31 strain in sodium dodecyl sulfate-polyacrylamide gel electrophoresis (note the similar protein bands in lanes B through G in Fig. 2).⁵³ These similarities among *B. burgdorferi* that originated from different sources suggest that similar-type spirochetes often are being circulated among wildlife and humans by the bite of *I. dammini*.

However, variants from the type B31 strain recently

have been isolated from larval *I. dammini* collected in upstate New York²⁰ and from cottontail rabbits and a rabbit tick known as *Ixodes dentatus*.⁴⁰ Note that some of the protein bands in lanes H and I in Fig. 2 have

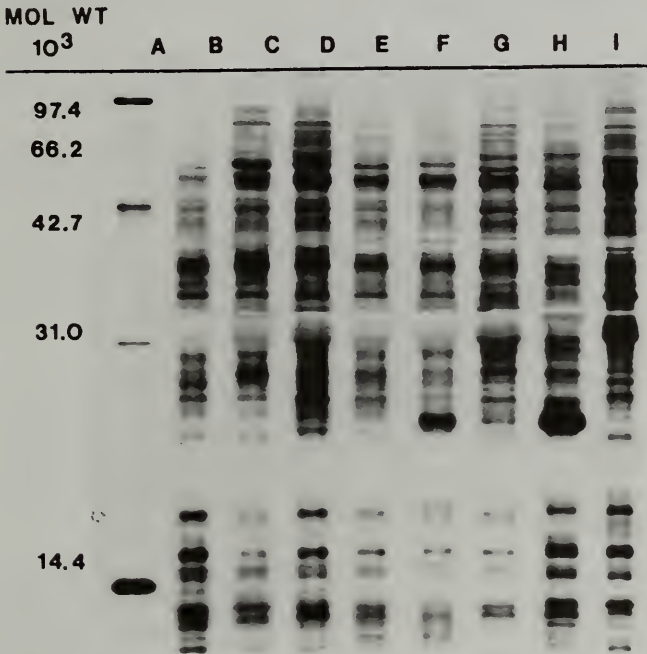


Figure 2

Whole-cell lysates of silver-stained *Borrelia burgdorferi* isolated from a human, ticks, and wildlife. Lanes: A, BioRad Laboratories, Rockville Center, New York, low molecular weight standards; B, *I. dammini* from Shelter Island, New York (strain B31); C, human from Connecticut (strain 297); D, white-footed mouse from Connecticut (strain 27947); E, meadow vole from Rhode Island (strain 26816); F, eastern chipmunk from Connecticut (strain 26815); G, *I. dammini* from Connecticut (strain 27985); H, *I. dammini* from upstate New York (strain 25015); I, cottontail rabbit from upstate New York (strain 19865).

distinctly different molecular weights from each other and from those in lanes B-G. Although it is unknown whether these variants cause disease in humans in North America, variants from the B31 strain of *B. burgdorferi* are infectious to humans in Europe.⁵⁴ Further studies are needed to determine the medical significance of these North American strains.

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Lyme Disease Prevention: Personal Protection and Prospects for Tick Control

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Introduction

THE presence of *Ixodes dammini*, the principal tick vector of *Borrelia burgdorferi*, has made outdoor activity in many areas of Connecticut a public health threat. The large number of Lyme disease cases in Connecticut and other areas of the northeast has been attributed to an abundant population of *I. dammini*, to elevated infection rates of *B. burgdorferi* in the tick vector, and to the close association between people and ticks in or near woodlands. Residential development in woodlands has helped to bring humans into close contact with *I. dammini*. Demand for information on personal protection measures and vector control has increased along with the number of human cases and public awareness of Lyme disease.

The chances of acquiring Lyme disease can be reduced by recognizing the tick, knowing where and when the tick may be found, and by taking several precautions while outdoors. The prompt and correct removal of ticks after discovery can further reduce the chances of infection.

There are several possible solutions for controlling ticks. The following measures are available to homeowners and public officials: host management or reduction, habitat modification, and chemical control. A fourth approach, biological control, is being investigated, but does not currently offer a practical solution for reducing *I. dammini*.

Personal Protection

Tick Identification

Among the 15 or more species of ticks found in Connecticut, the two most common are *Dermacentor variabilis*, the American dog tick, and *I. dammini*, often called the deer tick.¹ *Dermacentor variabilis* is found throughout the state while *I. dammini* is most abundant in the southeastern and southcentral portions of the state. Other tick species which attach to humans in Connecticut are *Amblyomma americanum*, the lone star tick,

Rhipicephalus sanguineus, the brown dog tick, and *I. cookei*.

Ixodes dammini is a small, reddish brown to dark brown tick. There are three active stages of the tick: immature larvae, nymphs, and sexually mature adults. Larvae are extremely minute (0.5 mm) and possess only six legs instead of the eight legs present on the other stages. Because transovarial transmission of *B. burgdorferi* is very low (usually < 2%), larvae are not considered to play a major role as vectors of the disease agent to people. Nymphs of *I. dammini* are about the size of a pinhead or freckle (1-2 mm) and are responsible for the majority of Lyme disease cases. Adult *I. dammini* are larger (2-3 mm). Females have a dark brown dorsal "shield" located behind the mouthparts, and when unengorged, have a reddish brown body. Males are slightly smaller than the female and are completely dark brown (Fig. 1).

Accurate identification of a tick is important in assessing a patient's risk of acquiring Lyme disease. It is relatively easy to distinguish adult *Dermacentor* ticks from *I. dammini*. Adult *D. variabilis* are generally much larger than adult *I. dammini* and the "shield" on the dog tick has a white mottled color pattern. Identification of the smaller immature stages and other species of ticks is difficult and should be done by a trained specialist.

Personal Preventive Measures

The best way to prevent Lyme disease is to avoid tick infested areas during the season when *I. dammini* nymphs are active: May, June, and July. *Ixodes dammini* is most abundant in woodlands, especially in areas of transitional vegetation with tall grass and shrubs, where mammalian and avian hosts for this tick flourish. Areas endemic for Lyme disease are commonly associated with undeveloped woodlands and parks. For example, studies of *I. dammini* densities in recreational parks in Westchester County, New York, showed a significant public health risk.² One of the parks with the highest level of public use also had the greatest *I. dammini* population index. Personal preventive measures could substantially reduce the risk of acquiring tick bites in

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Figure 1

Ixodes dammini adults, clockwise from right: unengorged female, male, and fully engorged female with egg mass. Cotton fibers from rearing container are visible at egg mass edge.

these areas.

Individuals who will be exposed to ticks should wear light-colored clothing and check themselves periodically. Wearing a hat and a long sleeve shirt with a snug collar and cuffs will give added protection. Pants should be tucked into the socks and only closed-toed shoes, no sandals, should be worn. Most ticks are picked up on the lower legs or feet and crawl upward to the head and neck. Hikers should walk in the center of trails to avoid the overhanging grass and brush. On returning home, clothing should be removed and washed. The body should be carefully inspected and any attached ticks quickly removed. Prompt removal of an attached tick with tweezers or forceps will reduce the chance of infection. Tick bites are usually painless and, consequently, many people may be unaware that they have been bitten. Children and pets should also be carefully inspected. The latter can bring ticks into the home, resulting in a human case of Lyme disease without the person being outdoors.

Tick Repellents

Repellents can increase the level of protection against tick bites. Most of these compounds are most effective when they are applied to clothing, particularly the shoe tops, socks, and pant cuffs. The standard chemical in most commercial repellents is N, N-diethylmeta-tolua-mide, called deet for short. An oily liquid, deet ranges in concentration from about 5% to nearly 100%. Individuals vary widely in their response to the feel and odor of deet.³ Some persons find that this material has a pleasant smell or no odor and does not feel oily, greasy, or sticky. Other individuals find deet uncomfortably oily or that it has an unpleasant odor. Deet may cause skin rashes and eruptions in some people, especially at maximum concentrations.

A newly registered repellent for mosquitoes, ticks, and chiggers, now available in Connecticut, contains permethrin, an insecticide which appears to provide high levels of protection against *I. dammini*.⁴ Permethrin is a synthetic pyrethroid that works primarily by killing ticks on contact. Unlike deet products, permethrin is registered only for use on the cloths and should not be applied to the skin. One treatment with permethrin should provide protection for one day or longer. According to the Connecticut label, clothing should not be retreated within 48 hours unless treated articles have been laundered between applications. In one study, a one-minute spray application of permethrin to the exterior surface of pants and jackets provided 100% protection against attack by all stages of *I. dammini*, while one-minute applications of 20% and 30% deet spray formulations provided 86% and 92% protection, respectively.⁴ Higher concentrations of deet and other repellents still need to be tested.

Tick Attachment and Removal

The mouthparts of a tick consist of two dorsal chelicerae and a ventral hypostome (Fig. 2). The hypostome is



Figure 2

Electron micrograph of adult *I. dammini* showing a ventral view of the two palps and hypostome (center). The palps are sensory structures which do not penetrate the skin. Photograph provided courtesy of Pfizer Central Research, used with permission.

covered by rows of denticles or "teeth" which help secure the tick to the host. Attachment to the host by the hypostome is strengthened by the secretion of an attachment substance. As a result of this firm attachment, the hypostome is often broken and separated from the body during removal.

Once attached, a feeding lesion develops within the host skin to provide a pool of blood for the feeding tick. Enzymatic secretions from the tick's salivary glands are

believed to dilate skin capillaries and enhance hemorrhaging by preventing blood coagulation. Several days are usually required for a larva or nymph to complete a blood meal. Adult females feed for longer durations. Prolonged feeding is an important factor in the transmission of disease agents by ticks. The rate of feeding is slow initially, but rapidly increases during the final period of attachment. Engorgement by *I. dammini* in the laboratory averages five days for the nymph and 9.3 days for the adult.⁵ The adult female takes a large blood meal and may enlarge to nearly the same size as an engorged American dog tick (Fig. 1).

The recommended method for tick removal is to use curved forceps or thin-tipped tweezers to grasp the tick as close to the skin surface as possible. The tick should then be pulled straight upward with steady even pressure.⁶ This should remove the tick with the mouthparts intact. Twisting or jerking the tick can break the mouthparts. Squeezing the engorged tick may release spirochetes or other tick tissues and fluids onto the skin. The tick should not be touched or crushed with bare hands as spirochetes may enter through breaks in the skin. Gloves or a tissue can be used while manually deticking pets. Once the tick is removed, the site can be disinfected with rubbing alcohol. Save the tick in a jar of alcohol for later identification. This information may become useful if an illness develops. Note the site of the bite and watch for symptoms of Lyme disease. Many ticks are not infected and, therefore, a tick bite does not necessarily mean a person will develop Lyme disease.

Several techniques for forcing a tick to "back out" are well established in folklore. Petroleum jelly, butter, kerosene, alcohol, fingernail polish, or hot burning matches will not induce detachment. Materials such as petroleum jelly are believed to suffocate the tick, but this only prolongs the time the tick is attached, which increases the chances of acquiring Lyme disease. The use of a hot match risks burning the person and may cause the tick to inject spirochetes into the skin or burst.

Tick Control

Host Management

Vector control by host management or reduction denies ticks access to a particular host by exclusion or removal of the animal. *Ixodes dammini* has a broad host range, attacking many mammalian and avian hosts. To date, immature and adult ticks have been found on 31 mammals and 49 species of birds.⁷ Host management has focused on two important mammals; white-footed mice, *Peromyscus leucopus*, and white-tailed deer, *Odocoileus virginianus*. The white-footed mouse is one of the primary hosts for larvae and nymphs of *I. dammini* and the principal reservoir of *B. burgdorferi*. The white-tailed deer is the preferred host for adult *I. dammini*.

The distribution and recent resurgence of deer populations has been closely linked to the presence and increased abundance of *I. dammini*.^{7,8} In many areas, deer have

exceeded both their biological and cultural (human tolerance) carrying capacities justifying deer population management programs.⁹ Deer overpopulation has resulted in deer-vehicle collisions and damage to forests, agricultural crops, ornamentals, and home gardens. Regulated hunting is believed to be an effective and economical option for deer population management⁹ and, with the link to Lyme disease, attitudes towards hunting deer in some communities have changed. The importance of deer in the distribution of *I. dammini* suggested the tick might be controlled by reducing or managing the deer population.

To study the impact of reducing deer numbers on the tick population, these animals were removed from Great Island, Massachusetts, beginning in 1982.¹⁰ Removal of 70% of the deer had no immediate impact on the tick population, but numbers of *I. dammini* larvae and nymphs declined when the deer were virtually eradicated. However, the adult *I. dammini* population has remained elevated for the three-year period following removal of the deer. Based on this study, it appears that deer would have to be totally eradicated to control *I. dammini*. Deer eradication as a control strategy against *I. dammini* would probably not be practical except on small islands or other geographically isolated areas.

Home construction and the creation of lawns produces an "edge effect" with diverse transitional vegetation favorable to important hosts of *I. dammini*. For homeowners, reducing the suitability of the habitat for mammalian and avian hosts can reduce the risk of exposure to *I. dammini*.

Rodent control measures could be directed toward the destruction or modification of mouse habitat around the home. Mowing the grass and clearing brush might also reduce the suitability of the habitat for small mammals. Potential mouse habitats such as rock walls should be kept brush free, and wood piles, favorable nesting sites, should be kept away from the house. Antirodent measures in highly endemic settings may increase pathogen transmission by increasing the density of ticks relative to each surviving mouse.

Birds may also bring ticks into the home environment. Therefore, feeders should be relocated away from the house, particularly during the summer months when immature stages of *I. dammini* are active. Birds are important hosts for larvae and nymphs of this tick and are probably responsible for expanding the geographic range of Lyme disease.¹¹ Scattered feed from bird feeders also provides food for other hosts such as mice and squirrels. Dogs and cats should be kept under control, if possible, and inspected regularly for ticks, because these animals can bring ticks into the lawn or home.

Habitat Modification

Vector control by habitat modification is based on alteration of the vegetation to produce an unfavorable environment for tick oviposition, hatch, molting, or

host-seeking. Ticks that seek vertebrate hosts are particularly vulnerable to desiccation because they leave sheltered places with favorable microclimatic conditions (eg, high relative humidity and moderate temperatures) to climb to the tips of the vegetation. Many activities which reduce the suitability of the habitat for hosts of *I. dammini* also make it less desirable for the tick. For example, mowing the vegetation, removing leaf litter accumulations, and clearing underbrush should raise the ambient temperature and lower the relative humidity of the habitat, which ultimately may help reduce the number of ticks. In the only vegetative alteration study for *I. dammini*, host-seeking adults were reduced by 70% for one year by mowing woodland brush.¹² In another study, burning vegetation reduced adult tick populations by 70% to 88.3% for up to one year.¹² This practice would be unacceptable in most residential areas and hardwood forests. A major problem with both these measures is that rapid regrowth may occur and the area may become more favorable for host animals.

Biological Control

Ixodes dammini is parasitized by a small wasp, *Hunterellus hookeri* Howard (Hymenoptera: Encyrtidae), but the wasp is relatively scarce in most areas where *I. dammini* now abounds. In contrast with the low rate of parasitism (< 1%) in several areas of Massachusetts, nearly a third of engorged *I. dammini* on Naushon Island, Massachusetts, were found to be parasitized by the wasp.¹³ This unusually intense *H. hookeri* population is probably derived from wasps released in 1926 to control the American dog tick, *Dermacentor variabilis*. No wasps were recovered from *D. variabilis* and no noticeable reduction in numbers of ticks were observed after this release or another on Martha's Vineyard. Unfortunately, the inability of the wasp to establish itself in substantial numbers leads one to conclude that it is ineffective in controlling *I. dammini* at the present time.

Chemical Control

Tick control by the application of pesticides to the habitat has many problems. Large-scale application of a pesticide requires a relatively large amount of material and raises serious environmental concerns. Furthermore, few materials are registered for area-wide outdoor use. However, three materials are registered for control of ticks and are available to the homeowner for treatment in or around the home or lawns. These are carbaryl (Sevin), chlorpyrifos (Dursban), and diazinon. A fall application of carbaryl or diazinon has been shown to reduce adult *I. dammini* populations in an oak-dominated forest for one year.¹⁴ However, pesticide applications would be in greatest demand by homeowners during the late spring and early summer when questing *I. dammini* nymphs are active and people are at the greatest risk of contracting Lyme disease. The nymph is the most important stage of the tick in pathogen transmission. Spray applications to densely wooded habitats often fail to penetrate the foliage to reach the ticks in the

soil, at the base of vegetation, or on hosts.

An alternative method of delivering a pesticide to target larval and nymphal *I. dammini* on white-footed mice has been recently developed and marketed commercially. Tubes of permethrin-treated cottonballs are placed at 10 meter intervals in mouse habitats. Mice collect the treated cotton for bedding material in their nests where the pesticide would kill *I. dammini* larvae and nymphs present on the mice or in the nest. The tubes are easy to disperse and appear to environmentally safe. Use of permethrin-treated cotton has reduced the infestation rate of immature ticks on white-footed mice in two studies conducted by the owners of the company.^{15,16} However, permethrin treated cotton did not appear to affect the host-seeking nymphal population until the second year of use and had no effect on ticks attached to voles. Additional field tests are needed to evaluate the effectiveness of this method in varying habitats and with the presence of different hosts. The impact of permethrin-treated cotton may be reduced by the tick's use of other hosts such as voles, gray squirrels, eastern chipmunks, and birds.

Other Potential Vectors

At the present time, only *Ixodes* ticks of the *I. ricinus* complex have been found to be competent vectors of the Lyme disease spirochetes. *Ixodes pacificus* transmits *B. burgdorferi* in the Pacific Coast States while other *Ixodes* species are the vectors of this bacterium in Europe and Asia. Antigenically variable *B. burgdorferi* have been isolated from *I. dentatus* on cottontail rabbits in New York, but this tick feeds primarily on rabbits, rarely on humans, and its role in the ecology of Lyme disease is unknown.¹⁷

Several non-*Ixodes* ticks; *D. variabilis*, *Amblyomma americanum*, and *Haemaphysalis leporispalustris*, have been found harboring *B. burgdorferi*. Only the lone star tick, *A. americanum*, is suspected of being a secondary vector of Lyme disease spirochetes.¹⁸ *Borrelia burgdorferi* were detected in adult and nymphal lone star ticks, including two in New Jersey taken from patients who had developed the characteristic skin lesion, erythema migrans. However, *A. americanum* was found to be an inefficient vector in the laboratory.¹⁹ The lone star tick is widely distributed in the southeastern United States, but significant populations of this species occur as far north as New Jersey. A few specimens have been found in Connecticut.¹ Personal protective measures used against *I. dammini* may also be used against *A. americanum*. The permethrin repellent has also been found effective against *A. americanum*.²⁰

Cases of Lyme disease have been reported from many states outside the distribution of *I. dammini* or *I. pacificus*, and the vectors in these areas remain unidentified.

The black-legged tick, *Ixodes scapularis*, has been found to be an efficient vector in the laboratory, but infection rates are extremely low or nonexistent in natu-

ral populations.¹⁹ This tick is widely distributed in the southeastern United States, and *I. dammini* was formally considered a northern variety of *I. scapularis*. The American dog tick, *D. variabilis*, is not considered a potential vector of *B. burgdorferi*.^{21,22} Infection rates of nymphs are relatively low and spirochetes are absent in questing adults. Infection of *B. burgdorferi* in *D. variabilis* in the laboratory is inefficient and short lived.¹⁹ *Dermacentor variabilis* is the primary vector of Rocky Mountain spotted fever in Connecticut, but the incidence of the disease and infection rates in the tick are low.²³

Several hematophagous insects have been found carrying *B. burgdorferi*. Spirochetes have been detected in several species of tabanids (deer flies and horse flies), mosquitoes, a flea, *Orchopeas leucopus*, and in a bot fly larva, *Cuterebra fontinella*.^{21,22} There are anecdotal records of erythema migrans associated with deer fly bites and a record of erythema migrans associated with mosquito bites in an individual in Sweden.²⁴ Deer flies and horse flies may mechanically transmit *B. burgdorferi* to people in areas where *I. dammini* and reservoir hosts maintain this agent in foci. However, transmission of *B. burgdorferi* by blood-sucking insects needs to be demonstrated. Mosquitoes are less likely to be important vectors of *B. burgdorferi*. Head tissues of field-collected specimens contained low numbers of spirochetes, and the etiologic agent could not be isolated from hamsters fed upon by infected mosquitoes.²¹ Repellents may offer some protection against biting flies, but no efficient control measures are available for deer flies and horse flies. The ability of ectoparasites, such as fleas, to harbor and transmit *B. burgdorferi* to humans or pets remains unknown.

Conclusions

While Lyme disease will continue to be a public health problem, the risk of acquiring the disease can be substantially reduced. At the present time, only *I. dammini* appears to be an efficient vector of *B. burgdorferi* in Connecticut. Large-scale solutions have not been developed to control *I. dammini*, but several options; host management, habitat modification, and chemical applications are available. These options are still being explored experimentally. If the public can be educated on how to recognize *I. dammini*, on the tick's life history and distribution, and on the proper precautions to follow to avoid tick bites, the outdoors can still be safe for work or recreation.

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Lyme Borreliosis in Domestic Animals

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Introduction

LYME borreliosis in domestic animals is a widely recognized clinical entity affecting a broad variety of species.¹⁻¹³ Practicing physicians may be asked about Lyme borreliosis in their patients' pets, especially in areas endemic for Lyme disease. Clinicians should be aware of Lyme borreliosis as a cause of veterinary illness and of the potential for animals to facilitate transmission of this disease to humans.

Lyme Borreliosis in Dogs

Arthritis is the most common form of Lyme borreliosis seen in dogs.¹⁻³ Gait abnormalities and reluctance to move are the most common symptoms, often accompanied by fever, lethargy, and loss of appetite. Arthritic dogs can have markedly elevated antibody titers to *Borrelia burgdorferi*. In my experience, response to antibiotics (10 to 14 days) and nonsteroidal anti-inflammatory drugs (NSAIDS) has been rapid with the greatest number of patients showing marked recovery within the first 24 hours of treatment.

Lyme nephritis and carditis are less common syndromes than arthritis. Carditis with complete heart block, ventricular escape, and idioventricular rhythms has been reported.⁶ Histologically, inflammatory infiltration with neutrophils, macrophages, lymphocytes, plasma cells, and spirochetal fragments was observed.⁶ Nephrotic dogs are uremic and hyperphosphatemic.^{4,5} Spirochetes have been observed in renal tissue,⁴ and membranoproliferative glomerular disease and tubular changes have been described.⁵

Lyme Borreliosis in Cats

In my practice, cats with signs of mild to moderate lameness, low-grade fever, and poor appetite have had positive antibody titers for *B. burgdorferi*. Treatment with amoxicillin has been followed by resolution of symptoms within days to one week. Typically, affected

cats present with nonspecific lameness often described as occurring when the pet jumps down from an object to the floor and exhibits pain upon landing.

Lyme Borreliosis in Horses

Arthritis, panuveitis, glomerulonephritis,⁷ lethargy, low-grade fever, stiffness, laminitis, reluctance to move,⁷⁻¹⁰ and encephalitis¹¹ have been observed in horses with positive antibody titers to *B. burgdorferi*. Therapy with antibiotics and NSAIDS has aided in resolution of symptoms.⁸

Lyme Borreliosis in Cows

Erythema of the ventral udder,¹² lameness, swelling of the distal joints of the limbs,^{10,12,13} weight loss, laminitis, and abortion¹⁰ have been observed in cows with positive antibody titers to *B. burgdorferi*. Therapy with intravenous tetracycline produced resolution of signs in three to five days in one study.¹²

Tick Control for Domestic Animals

A comprehensive program of tick control for dogs and cats includes the use of tick collars, sprays, baths, and dips. All of the above will kill ticks. Some sprays such as those that contain permethrin will repel ticks. The repellent capabilities of most common flea and tick products have yet to be determined. Dogs and cats may wear an organophosphate collar and be treated at suitable intervals with either a pyrethrin or organophosphate spray or powder. It is essential that the veterinarian tailor the program for each species and individual patient taking into consideration the potential for additive exposure to these products and individual species sensitivities.

Environmental control includes cutting brush and mowing grass in animal areas. This creates an environment that is inhospitable for the tick and less likely to harbor the small mammals that host the immature stages of the tick. Ideal environmental control for yards includes fencing, mowing, and area spraying with insecticides.

Domestic Animals and Human Lyme Disease

The extent to which domestic animals place their human owners at increased risk for acquiring Lyme disease is unknown. Although this issue is frequently raised by pet owners, it has not been definitively resolved. In their 1977 paper identifying Lyme disease as a distinct

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clinical entity in man,¹⁴ Dr. Steere et al described a possible relationship between pet ownership and developing Lyme disease when it was determined that only three of the families in the study group did not own pets. In another study, one adult and eight nymphal *Ixodes dammini* were collected from two free roaming cats when they returned to their home from outside.¹⁵ These cats are believed to have been the source of a tick which transmitted Lyme disease to one of the researchers.

Several authors have raised the possibility that domestic animals may serve as a potential source of human infection via nontick transmission of *B. burgdorferi*, for example through urine^{5,10,12} or milk^{10,12} that harbor spirochetes or cause seroconversion in exposed experimental animals. In one case report, a man developed erythema migrans and a positive antibody titer to *B. burgdorferi* after being bitten by a sick horse.¹⁶ Experimental evidence has been found for nontick contact transmission in animals, although the risk of transmission is unknown.¹⁷⁻¹⁹

Discussion

Diagnosis of Lyme borreliosis in animals must take into account clinical signs and symptoms, potential for exposure to infected ticks, and the results of serologic testing. In all suspected cases, good clinical judgement may be the most important factor in medical management. The relative efficacy of various antibiotics and NSAIDS must be evaluated in controlled studies.

Pet ownership involves many activities that take place in tick habitats. Following a hunting dog in search of upland game birds, riding a horse, or walking along a grassy roadside with a dog may expose a person to ticks. Veterinarians are helping to educate the public about Lyme borreliosis in animals and humans. Increased awareness of Lyme borreliosis and its prevention and early detection should assure our continued enjoyment of our domesticated animals.

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Lyme Disease Prevention—Knowledge, Beliefs, and Behaviors among High School Students in an Endemic Area

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ABSTRACT—We surveyed 153 high school students in an area highly-endemic for Lyme disease. All students were familiar with Lyme disease; 14 students reported having had the disease. Ninety per cent of students believed tick-avoidance behavior could prevent Lyme disease, but fewer than half reported practicing any preventive behaviors. Students who believed a specific behavior was preventive were 3-6 times more likely than others to practice that behavior. Schools in endemic areas should educate students about Lyme disease.

LYME disease is a tick-borne illness first described in Lyme, Connecticut in 1975. The disease is now recognized as a major public health problem in the United States and abroad. From 1984 through 1986, the Centers for Disease Control (CDC) received an average of 1,500 reports of Lyme disease annually, making it the most common tick-borne disease reported to CDC.^{1,2}

Since practical methods of tick control have not yet been developed, the best way to prevent Lyme disease is through education about the disease and the importance of avoiding tick bites. Because Lyme disease is particularly common among children and young adults, education programs should be targeted toward the younger population.

A key question is whether education is successful in

persuading young people to change their behavior in such a way that will decrease their risk of exposure. We conducted a survey of eleventh- and twelfth-graders in a Lyme disease-endemic area to ascertain how much they know about Lyme disease and whether that knowledge affected their behavior and their attitudes toward prevention.

Methods

Old Lyme, Connecticut, a coastal town east of the Connecticut River, is in an area endemic for Lyme disease. The regional high school in Old Lyme draws students from the town of Old Lyme (population 6,600) as well as the towns of Lyme, South Lyme, and Hadlyme (combined population 1,930). Despite the high incidence of Lyme disease in this region, education about Lyme disease has not been a formal part of the health curriculum at the school. On October 29, 1987, self-administered questionnaires were given to the 153 eleventh- and twelfth-grade students who attended physical education class that day (78 percent of the entire 11th- and 12th-grades). The questionnaire gathered basic demographic data and contained 54 questions regarding the student's knowledge, beliefs, and behavior regarding Lyme disease. The questionnaire also asked students if they had had Lyme disease in the past, and if so, what their symptoms were.

Statistical tests included 95% confidence intervals (95% CI) for relative risks obtained by the Taylor series approach.³

Results

Knowledge and Beliefs

All 153 students reported that they had heard of Lyme disease. Ninety-nine students (65%) believed that Lyme disease was a "serious" or "very serious" illness. The majority of students (78%) believed that Lyme was a "common" or "very common" disease in Connecticut.

When asked about disease transmission, 127 students (83%) knew that Lyme disease is transmitted by the bite of a deer tick, and 55 (36%) knew that it was not acquired through the bite of a dog tick.

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When asked about preventive measures, 136 students (89%) indicated that they could lower their chance of catching Lyme disease by wearing long-sleeved shirts and long pants when in wooded and grassy areas (Table 1). Similarly, 141 (92%) believed that removing ticks from themselves after walking in wooded or grassy areas would reduce their chances of catching the disease. There were no substantial differences in Lyme disease knowledge or beliefs by gender or grade in school.

Table 1
Junior and Senior High School Student's Knowledge and Beliefs about Lyme Disease Prevention, Lyme - Old Lyme High School, Connecticut, 1987

Statement presented to students: You can lower your chance of catching Lyme disease by _____:	Correct Response	% of Students (N=153)		
		Agree	Disagree	Don't Know
Wearing long-sleeved shirts and long pants when in wooded or grassy areas	Agree	89	6	5
Looking for insects on yourself and removing them after walking in wooded or grassy areas	Agree	92	3	5
Using insect repellent on your skin and your clothes	Agree	60	22	19
Avoiding people who have Lyme disease	Disagree	2	86	12

Behaviors

Seventy-four students (48%) reported that they checked themselves for ticks “always” or “often” after walking in wooded or grassy areas (Table 2). Students who believed that removing ticks prevented Lyme disease were more likely to practice it than students who did not (51% [72/141] vs. 17% [2/12], RR=3.1, 95% CI=0.9,11.0). Among the 141 students who believed that removing ticks might prevent Lyme disease, those who thought Lyme disease was “serious” or “very serious” were more likely than others to practice this behavior (57% [54/95] vs. 39% [18/46], RR=1.5, 95% CI=1.0,2.2).

Only 49 students (32%) reported wearing long-sleeved shirts and pants “always” or “often” when walking in wooded or grassy areas (Table 2). Students who thought wearing long-sleeved shirts and pants might prevent

Table 2
Junior and Senior High School Student's Lyme Disease Prevention Behaviors, Lyme - Old Lyme, Connecticut, 1987

Statement presented to students: In the last year, how often have you done each of the following _____:	% of Students (N=153)
	Always/Often
Wear long-sleeved shirts and long pants when in wooded or grassy areas	32
Look for insects on yourself and remove them after walking in wooded or grassy areas	48
Use insect repellent on your skin and your clothes	17
Avoid people who have Lyme disease	3

Lyme disease were more likely to practice this behavior than those who did not (35% [48/136] vs. 17% [1/17], RR=6.0, 95% CI=0.9,40.7). Among the 136 students knowledgeable about this behavior, there was no association between the attitude that the disease was “serious” and the use of long-sleeved shirts and pants (38% [35/93] vs. 30% [13/43], RR=1.2, 95% CI=0.7,2.1).

Self-reported Lyme Disease

Fourteen students (9%) reported having been told by a doctor that they had had Lyme disease. Ten of these students stated that they had had a positive Lyme disease blood test. The most common symptoms reported were fatigue (12), joint pains (11), fever (10), rash (10), and headache (9).

These 14 students were no more knowledgeable about Lyme disease prevention than their classmates; the relative risks for all prevention-related knowledge items were less than 1.2. They were slightly more likely than their classmates to check for ticks (79% [11/14] vs. 45% [62/138], RR=1.8, 95% CI=1.3,2.4) and to wear long-sleeved shirts and long pants (43% [6/14] vs. 31% [43/139], RR=1.4, 95% CI=0.7,2.7, p=.54).

Education

The most important sources of information about Lyme disease reported by students were parents (45%), doctors/nurses (24%), and friends (19%). Only six students (4%) stated that their most important source of information was teachers. Sixty-eight students (44%) wanted to learn more about Lyme disease; lectures (32%) and videos (29%) were listed most frequently by these students as preferred ways to learn about the disease.

Discussion

In general, we found these high school students in an endemic area to be knowledgeable about Lyme disease. Students generally recognized that Lyme disease was a serious and common disease. In addition, nearly one student in 10 had had self-reported Lyme disease. In spite of this, the majority of the students did not practice preventive behaviors.

Our data suggest that students who knew that a specific behavior could decrease their chance of getting Lyme disease were more likely than others to practice that behavior. Among the students who knew about the preventive behaviors, those who believed that Lyme disease was a serious disease were more likely to practice tick removal, although a similar inclination was not found for the wearing of long-sleeved shirts and pants. Because this was a descriptive study, these findings need to be confirmed by additional studies.

In Rosenstock's health belief model,⁴ a person is more likely to practice preventive behaviors if he believes that the disease is serious and he is at high risk for acquiring the disease, and that some course of action open to him will be effective in reducing the risk. Lyme disease is a serious illness and the risk of acquiring Lyme disease can be high in areas endemic for Lyme disease.⁵ Unfortu-

nately, the effectiveness of the commonly recommended prevention techniques in reducing the incidence of Lyme disease has not been determined. For some, the prevention measures are inconvenient and not readily accepted. The wearing of long-sleeved shirts and pants in tick-infested areas can be a difficult measure to practice in the summer months when the risk of acquiring Lyme disease is greatest. According to Spielman,⁶ highly motivated persons can gain some personal protection against Lyme disease. These issues pose a problem for the success of Lyme disease prevention efforts.

Children are at particularly high risk for acquiring Lyme disease. In Connecticut in 1985, the age-specific incidence of Lyme disease by 5-year age groups was highest in those aged 5 to 9 years (39/100,000).¹ Educating children and adolescents about Lyme disease prevention may not be an easy task. Education that emphasizes the risks of acquiring Lyme disease may not be very effective for young people, especially considering the sense of personal invulnerability that is common in adolescence.^{7,8} School health educators have dealt with similar problems when designing educational programs about drug abuse (including alcohol and tobacco) and the acquired immunodeficiency syndrome.^{8,9}

In our study, only a very small percentage of students had learned about Lyme disease from teachers. At the same time, nearly half of the students expressed interest in learning more about Lyme disease. The task for school health educators is to provide information in a way that motivates students. We believe that schools can be effective sources of Lyme disease education in endemic areas and that we would do well to involve school health

educators now in the problem of Lyme disease education. Because Lyme disease is an increasing public health problem in the United States, education about Lyme disease should be given a higher priority by both schools and health departments, especially in areas endemic for Lyme disease.

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Catching the Bug: How Scientists Found the Cause of Lyme Disease and Why We're Not Out of the Woods Yet

JOEL LANG

IN hindsight, it appears that the first symptom of Lyme disease was recognized formally as long ago as 1908, in Sweden. The symptom was an awful-looking rash called erythema chronicum migrans that could persist for days while expanding its perimeter—in effect, migrating. Around the edge of the rash, the skin tended to be raised and red, while in the center the skin was stretched hard and white. The rash might be said to resemble a ring of low mountains enclosing a desert. Though it felt more hot than itchy, the rash could be frightening because of its size. Erythema chronicum migrans, soon known by its acronym ECM, could grow to more than a foot wide.

In the decades that followed, ECM was noted elsewhere in Europe as were other symptoms that seemed to follow ECM's eruption. Those secondary symptoms, which were described variously in France, Germany, and again in Sweden, generally involved impairment of the nervous system. The most common came to be grouped in a syndrome that included meningitis-like headaches and stiffness of the neck as well as vague pain in the arms and legs and, occasionally, a feeling of overwhelming fatigue.

When penicillin became widely available after World War II, it was used to treat ECM and its associated ailments. A more incidental piece of information about ECM, one reported by the Swedish dermatologists who originally described the rash, was that it appeared on some victims soon after they had been bitten by a tick. Indeed, the rash seemed to radiate from the point of the bite. The culprit was identified as *Ixodes ricinus*, the sheep tick common throughout Europe.

Neither the rash nor the neurological ailments created much of a stir. Their descriptions and protocols were absorbed quietly into the body of European medical

literature. The connections between tick, rash, and neurological disease were there to be examined, if anyone chose. Few did.

In the United States, the European rash was virtually unknown. Its first incidence here was reported in 1969 by a physician who had been bitten by a tick while hunting for grouse in Wisconsin. Subsequently, a few ECM cases were seen in Americans who had traveled to Europe, but there were no further native American cases until 1975 when doctors at the U.S. Navy base in Groton, Connecticut, reported seeing a similar rash on four of their patients. None of the patients recalled having been bitten by a tick.

Coincidentally that same year, two women who lived in tranquil, densely wooded towns on the lower reaches of the Connecticut River began to complain publicly about health problems far more mysterious and threatening than any rash.

In the case of one, Judith Mensch of Old Lyme, it was not her own health, but her eight-year-old daughter's that was worrisome. At first Anne Mensch's illness seemed trivial. On Halloween, she came home from school with a swollen knee and her mother assumed it was the result of a fall. But when the swelling persisted the next day, Mensch made an appointment to take Anne to an orthopedic surgeon. The surgeon quickly diagnosed osteomyelitis, an infection of the bone with potentially grave consequences. Since the suspected cause of osteomyelitis was an invasion of bacteria, the surgeon put Anne on a rigorous treatment of antibiotics. She was admitted to Lawrence & Memorial Hospitals in New London where large doses could be administered intravenously. Meanwhile the surgeon drained the knee and sent a sample of the fluid to the laboratory for analysis. By the next morning, both Anne's knees were swollen so badly she couldn't move them.

The lab tests for bacterial infection came back negative, as did another series of tests that Anne's father, staff pathologist at Lawrence & Memorial, had ordered for viral infection. With no apparent cause for her illness, the

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intravenous antibiotics were stopped after several days, and Anne was sent home in a wheelchair. Her treatment was switched to 10 aspirin a day, an enormous dosage for a child who weighed 40 pounds. Aspirin was the medicine commonly prescribed for juvenile rheumatoid arthritis, which was what doctors, unable to find evidence of any other disease, eventually decided Anne must have. The diagnosis was more descriptive than conclusive, however. Arthritis is not strictly a disease; it refers to the inflammation of joints that can be a symptom of more than a hundred specific diseases for which there is often no known cure or cause. Anne Mensch was said to have juvenile rheumatoid arthritis because it fit her condition: She was young and her knees inflamed so badly she could barely walk. If she had a rash, it was faint enough to escape notice.

Judith Mensch, however, refused to accept the diagnosis. She was motivated partly by denial; she did not want to believe her daughter had a possibly incurable disease that might leave her crippled. But Mensch was skeptical for another reason, too. She knew three other children nearby who also had been diagnosed as having arthritis. It didn't make sense to Mensch, who was aware that juvenile rheumatoid arthritis was a relatively rare, noncontagious disease.

Searching for an explanation for her daughter's disease, Mensch began telephoning local doctors and talking to townspeople she bumped into at the supermarket or library. Eventually she called the Connecticut Department of Health Services, which informed her the state could do nothing since this kind of arthritis was not contagious. She then called the federal government's Centers for Disease Control (then known as the Communicable Disease Center) in Atlanta, which started to tell her the same thing.

Worried and frustrated, Mensch blew up on the phone, using language, she said later, that she preferred to forget. The stunned person on the other end of the line in Atlanta at least transferred the call to someone more sympathetic. He suggested she call Allen Steere, a young doctor just beginning postgraduate research in rheumatology at the Yale School of Medicine.

It was only coincidence that the doctor Mensch spoke to knew Steere. It turned out that both men had worked at the Centers for Disease Control, where Steere had been attached to the Epidemic Intelligence Service. The service was a sort of medical commando corps trained to move quickly to investigate inexplicable outbreaks of disease. Before the year was out, Anne Mensch had become one of Allen Steere's patients, though by then the worst of her symptoms had subsided.

* * *

The second woman who undertook her own public health campaign was Polly Murray, whose ordeal made the Mensch's look like a picnic. Murray, a painter, lived with her husband and four children on Joshua Town Road in Lyme. One rambling country house surrounded by trim stone walls and dense woods follows another in

the road's twisting passage from the picturesque hamlet of Hamburg to the equally picturesque hamlet of Hadlyme on the banks of the Connecticut River. Protected, peaceful, pretty, it is the kind of road where almost any family would like to live. Living on Joshua Town Road, however, made Murray and her whole family sick.

By 1975, Polly Murray hardly remembered what it was like to be healthy. Looking back, she thought her illnesses might have started soon after the family moved to Lyme in 1959. But it took years for Murray to begin to see a pattern in the illnesses and to begin keeping a record of them. As it is, she is likely to refer to notes when reciting the history of her health problems and her family's.

Her first rashes appeared on her face and hand sometime in the 1960s; she thought one might have resulted from the scratch from a rose thorn. In 1967, she had a series of rashes accompanied by a swollen knee that were thought to be symptoms of rheumatic fever. In 1971, she was sick for months with one thing or another: terrible headaches, rashes and other skin problems, sore throats, and stiff joints. Her hands became so sore she had to give up painting. She went to major medical centers in Connecticut and Massachusetts for tests that proved uniformly inconclusive. "They tested for everything possible," she recalled. "Each symptom seemed to have four different diagnoses."

Soon Murray, who in her youth had worked in a hospital and for the World Health Organization, began to try to diagnose her own illness. She spent hours in the Yale Medical Library and came to wonder, like a few of the doctors she saw, whether she had lupus, a rare disease whose primary symptoms are skin and joint disorders. Lupus victims tended to react badly to sunlight, as did Murray. She also suffered in common with early lupus victims the psychological trauma that accompanies a disease so rare it is often misdiagnosed.

"Every time a doctor would see me, they'd come up with their own ideas and when their tests came back negative, they wouldn't know what to do. They said I couldn't have a disease because I didn't have a disease [they recognized]. It seemed on one hand I was dealing with something that was very real in terms of symptoms, but which on the other hand didn't exist in medical literature."

Doctors, trained to cure, became frustrated at their own failure. Eventually, some doctors would look at Murray's lengthening medical record and automatically reject her as a hypochondriac. For a time, even her family doubted her illness had a biological basis and, at the worst moments, she doubted it herself. It was particularly frustrating that she'd often schedule appointments with one specialist or another, only to find her symptoms temporarily gone when she arrived for examination.

The skepticism of some doctors was so great that in the mid-1970s, when her family began to develop some of the same symptoms Murray had had for years, they insinuated that her family was merely mimicking her neurotic behavior. Her family's symptoms, however,

were as real as her own. In summer 1974, her husband Gillis developed a stiffness in his knees; that Christmas her oldest son, Sandy, was knocked flat. Most of his joints ached, his whole upper body was stiff, one of his eyelids drooped, and he had a fever. The entire episode had started with a severe rash. Ten days later, all his symptoms had disappeared. Doctors thought he may have had a virus. Dogs, for instance, became lame for no apparent reason, then recovered.

Summer 1975 was the worst. For a while, the whole Murray family was ill. One morning in August, Murray woke up to discover that two of her sons, Sandy, then 18, and Todd, then 12, could barely walk. Earlier that summer, Todd, recently returned from a camping expedition on Block Island, experienced such pain and stiffness in his legs that he had to be carried to the car to be driven to the doctor.

By then, Murray had heard of other children with similar ailments. By then, she estimated she and her family had seen more than two dozen doctors.

"What I was looking for," said Murray, "was one doctor who would say, 'OK, something is going on here. Let's put everything in a computer and see what happens.'"

For a while she had hoped that that doctor was a specialist in Boston she had begun seeing in 1973. He at least had believed that her illness, whatever it was, was genuine. But by 1975, he determined that he could do nothing more and advised Murray that whatever disease was afflicting her, her family, and others in Lyme, it ought to be brought to the attention of the state health department.

As chance would have it, Murray called the department on 16 October only a few weeks before Mensch. Like Mensch, Murray was listened to perfunctorily. However, in November, some weeks after her initial call, Murray got a more solid response. It happened that the department's acting epidemiologist, Dr. David Snyderman, had been on vacation when the women called the first time. He returned to find a note left by his stand-in mentioning something about arthritis cases among children in the Lyme area.

"The [fill-in] physician was an older man," Snyderman recalled. "He didn't do anything a lot of people wouldn't have done. His thought was that arthritis wasn't infectious and that she [Murray] was all wet, or something to that effect." But Snyderman, who is now epidemiologist at the New England Medical Center and an associate professor at Tufts University School of Medicine, knew that juvenile arthritis occasionally does occur in clusters and that there were viruses that could cause its symptoms.

As chance would have it also, Snyderman, like the doctor Mensch spoke to at the Centers for Disease Control, knew Allen Steere. Snyderman in fact was on loan to the state from the center's Epidemic Intelligence Service.

In short order, Snyderman gathered enough information to establish that the towns did indeed seem to have "an awful lot of arthritis." Snyderman then called Steere and asked him if he would be willing to examine all the apparent arthritis victims he could round up.

* * *

When Steere got Snyderman's call, he had been at Yale only about four months and was groping for a focus to his research. He had come to the medical school on a fellowship underwritten by the Connecticut Arthritis Foundation and was beginning with basic research on white blood cells, the cells that fight infection. "It was a lot of straight lab work. I didn't like it very much," said Steere. "I was searching for something more interesting."

In fact, Steere's training as a physician had been a little out of the ordinary. A native of Indiana, he had gone to Columbia University College of Physicians & Surgeons, but during his final year he had spent three months in Liberia, where the principal diseases were infectious, in other words caused by bacteria, parasites, or other microscopic invaders. Later, his stint at the Centers for Disease Control had sent him to hospitals where there had been outbreaks of disease. On one occasion, for instance, he went to a hospital in Maine where an epidemic of diarrhea had broken out on the orthopedic ward. Steere traced the diarrhea to salmonella bacteria which in turn was traced to egg nog and ultimately to the hospital's egg supplier.

The call from Snyderman did not exactly cause Steere to see a blinding flash of light and rush from his lab to Lyme, however.

"David called and said, 'I've had these two calls from mothers who say there's been an outbreak of juvenile rheumatoid arthritis. What do you think of that?'" Steere remembered. "I said, 'Well, if it's true, it's never happened before.'"

Steere, nevertheless, was quite anxious to examine victims of the doubtful epidemic. The onset of a disease is a good time to look for causes, he figured, and if the Lyme people did have a form of arthritis, he might find important clues. Besides, Steere, like Snyderman, had been trained not to dismiss things just because they had no pattern.

"At the CDC, that's what you do: You take phone calls and listen," said Steere. "That's where you begin—with a phone call. And you go ahead whether it seems right or not."

Encouraged by his supervisor, Dr. Stephen Malawista, and careful not to offend local physicians who might consider him a high-handed interloper, Steere began to identify and examine supposed arthritis victims. The mothers were particularly helpful. Murray, in fact, brought a list of 37 names along to her first appointment with Steere. Those on the list had been diagnosed as having lupus, ringworm, and multiple sclerosis, among other things. (She remembers that visit on 20 November 1975, as a turning point. "That afternoon, I really felt that that was the beginning. Something existed where it didn't before." Ironically, at the time, Murray felt fine.)

Within four months, 51 people—39 children and 12 adults—had been identified as having the mystery disease. The common denominator was arthritis in the larger joints, most often in the knee. Given the array of symptoms the Murrys suffered, that early assessment

may seem too limited. But the initial calls to the state health department had mentioned children with arthritis and that was the symptom the epidemiologists pursued in Old Lyme, Lyme, and the next town north of the river, East Haddam. Besides, what the children had did indeed look a lot like juvenile rheumatoid arthritis (JRA).

Steere, however, could not bring himself to conclude it was JRA. For one thing, adults had the disease, too, and he was baffled by its intermittent nature. JRA was persistent. In Lyme, the arthritis came and went inexplicably. Then there was the strange concentration of cases.

"It really was marked by clusterings," Steere recalled. "On some streets it was one house after another. I can't tell you how different that is from JRA. I had been given a list of names to telephone. Once I dialed the wrong number and got a home where the kid had arthritis.

"Wherever you have a cluster of people with the same disease, what you try to do is to understand where their histories intersect. You ask where they were, what their previous illnesses were, what food they ate, what medications they took. You're looking for the common thread. But I couldn't find one."

Still, as he assembled case histories over the winter, Steere gradually distilled out other important bits of information. It appeared that many of his patients had first noticed their illnesses in the summer and early fall. Epidemiologically, this meant the clustering of the disease was seasonal as well as geographical.

If the disease was infectious, as it seemed to be because there were so many cases so close together, then a living organism was spreading it. The possibility that drinking water was the source of the infectious organism intrigued Steere for a while. Whatever organism it was, summer would likely be its breeding time if it did live in water. But in Lyme, most people got their water from wells, and no one knew where the wells might connect deep underground. Nor could water explain why, on many occasions, one person in a family had the disease and no one else did.

The meager evidence seemed to favor what technically was called a vector-borne disease, one carried by an insect. (The most infamous vector-borne disease in history was bubonic plague, the vector, a flea). Insects also reached their peak populations in the summer, Lyme was a wooded area with a lot of insects, and insects bit randomly. Also, a few of the adult patients remembered having what they thought was an insect bite that resulted in a frightening rash.

"They usually described it as a big, huge, expanding lesion that in some instances became enormous," Steere said.

Steere could only guess at what this strange rash actually looked like. He happened to see the patients in winter, when the rash had long since disappeared. Of course, the bug suspected of causing it was long gone, too. Whatever it was, it must have been small. None of Steere's early patients clearly remembered actually being bitten.

By the spring of 1976, Steere had not discovered the "common thread" he was seeking, but he had glimpses of it. In a letter dated 18 May to the 51 people he had examined in the four months after Syndman called, Steere summarized his findings. Arthritis, most frequently in the knee, was the defining symptom of the disease, though it was likely to begin with a rash. It occurred in the summer in clusters, suggesting it was vector-borne. It was probably a viral disease. Steere concluded that the disease abroad in the river towns was apparently a previously unknown form of arthritis.

* * *

Medically, this was an extraordinary and daring finding. Doctors declare new diseases with the trepidation and excitement akin to that which might accompany an astronomer's discovery of a new galaxy or an archaeologist's discovery of a pharaoh's tomb. Peers were likely to be skeptical; a reputation could be made or ruined. In Steere's case, there was another risk. The announcement of a new disease, especially one with no known cause or cure, could stigmatize the towns where it had been found and possibly precipitate a panic.

The disease even acquired a name. "I was seeing these people from Lyme. They had arthritis and so that became Lyme arthritis," Steere recalled. "You had to call it something."

The people of Lyme, Old Lyme, and East Haddam reacted with concern. Mostly they wanted to know how to protect themselves and their children, though there was some fear real estate values would fall. The rest of the world was merely fascinated. A copy of Steere's three-page letter found its way to a local newspaper, other publications got interested and by the summer of 1976, Lyme arthritis was a celebrity disease. (The summer before, Legionnaire's disease had been the big story.) "The Trouble in Lyme," was the headline on a story in *Newsweek*. A long story in the *New York Times* said a scientific detective process had begun that had turned "the fears of 'hysterical mothers' into medical history."

Later the tabloids picked up the story. "Mystery Illness Cripples Victims in Three Towns," declared the *Star*. The media started to pursue Polly Murray, whose case history was soon known by millions. The recognition was partial consolation for her many rejections by the medical establishment. She wondered whether the disease would have gotten the same amount of attention if it had not crystallized around children. In a 1981 letter to the *New England Journal of Medicine*, she suggested doctors confronted with the unknown may be too willing to dismiss a patient as hypochondriacal. At the time, she referred to the disease as "my discovery." Judith Mensch escaped much of the media spotlight. In the summer of 1976, she moved with her family to a Maryland suburb of Washington, D.C. Her daughter Anne seemed fully recovered, though no one knew why.

Indeed, the apparent discovery of a new disease raised far more questions about what was happening in Lyme and its neighboring towns than it answered. If a virus was

suspected of causing the illness, what virus was it? What insect carried it? Were either the insect or the virus peculiar to the Lyme area, or did they exist elsewhere, and did those places also have "epidemics" of arthritis? What was the cure?

The questions were too numerous and varied for Steere to tackle alone. Like so much of modern science, the investigation of the new disease known as Lyme arthritis became a collaborative effort. An epidemiology team from Yale took to the woods in the Lyme area searching for the disease "vector," as did entomologists at the Connecticut Agricultural Experiment Station in New Haven. Soon the search was joined on Long Island by scientists from the New York Health Department and on islands off the Massachusetts coast by scientists from the tropical diseases department at Harvard's School of Public Health.

In the summer of 1976, Steere zeroed in on the rash that so many of his original patients had described. The rash seemed to mark the onset of the disease, and he had stumbled onto some information that linked it with a tick. A fellow physician at Yale happened to mention that the previous summer two Navy doctors from Groton attending a conference at Yale had reported seeing a rash that sounded very much like Steere's. The Yale doctor, a dermatologist, guessed it might be related to the European ailment known as erythema chronicum migrans (ECM). Steere looked up ECM in a textbook.

"It was right there, described as a curiosity thought to be caused by a tick bite," said Steere. "But no real disease was associated with it. Nothing at all was said about arthritis."

Among Steere's original patients, only one thought he had been bitten by a tick, but many of them suddenly realized that, yes, they had noticed more ticks about. "It [the tick explosion] was kind of a new phenomenon," said Steere. "It started in 1965 and by the '70s, they were just terrible."

While others searched for the tick, Steere watched for the rash to appear. Eventually that summer, he saw what he thought were 12 cases. Steere, however, would not be absolutely sure the rash was the one connected with the new disease until months later, when some of the people who had the rash developed arthritis. The delay was a reminder of how rigorous and frustrating the quest for scientific truth can be. It was also a reminder of how tricky the quest can be. Steere thought that arthritis was the defining aspect of the new disease, so without arthritis he could not presume that other symptoms he saw or heard about were part of the disease.

Steere also thought that the disease was caused by a virus. His reasoning was mostly circumstantial. The intermittent nature of the arthritis suggested a virus, as did the absence of pus and white blood cells in the victims' inflamed joints. In a person with a bacterial infection, white blood cells increase to fight the intruder. Also Steere knew that bacterial diseases tended to be well documented and that bacteria were usually easier to detect in blood and tissue samples. The logic, essentially,

was if it's a mystery disease, it's probably viral.

Steere's was a mind at odds with itself. On one hand, he was seeking to describe, to classify, a disease that had not been seen before. On the other hand, he had to keep himself from leaping to conclusions about what the disease was. And the more patients he saw, the more confusing the disease appeared. Symptoms seemed to multiply. Soon after developing the rash, some patients came down with what seemed to be a bad flu. They complained of excruciating headaches, headaches so severe it felt as if their heads were splitting apart. They complained of fatigue so profound that it was an effort to get out of bed. More parts of the body than joints became inflamed. Steere began to see occasional cases of inflammation of the lining of the brain (meningitis), the brain itself (encephalitis), and, more rarely, of the heart (carditis).

* * *

Making an educated guess that the cause of all this pain was a virus, Steere initially treated his patients, if they actually had symptoms at the time he saw them, with aspirin. Nothing suggested antibiotics might help. But the research path Steere had started down was a long one. Each patient who came to him—the sooner after the onset of the disease the better—he would follow for months and years. What he found after the first examination would be what became important.

The pursuit of the tick suspected of transmitting the disease was no less time consuming. There was, of course, no hard proof that a tick was responsible. There was only the European textbook testimony about ECM and a couple of cases in this country where people who had developed the rash found a tick and saved it. Each tick, one from California and the other from Connecticut, was found to belong to the same genus as the European sheep tick. Neither was as large as the tick with which most people are familiar, the dog tick, which can swell to such repugnant size with blood.

All ticks, however, suck blood and as such they are efficient conduits of disease. The tick's history is ancient and sinister. Almost two millennia ago, the Roman writer Pliny the Elder described "an animal...living on blood with its head always fixed and swelling. Being of the animals which has not exit for its food, it bursts with over-repletion and dies from actual nourishment."

The myth that ticks die in an orgy of eating persists to this day. In fact, adult female ticks, once they have gorged themselves, drop off their hosts and then lay their eggs. The adult itself may or may not survive to another season. It is not a myth, however, that ticks are hard to remove. Most attach themselves with a barbed appendage called a hypostome that penetrates the skin and then is cemented in place by an enzyme secretion. When the tick has eaten, another secretion dissolves the "cement."

Some 800 species of ticks have been identified in the world, and 21 are known to exist in Connecticut. Until recently, the tick-borne disease most threatening in this country was Rocky Mountain spotted fever, whose symp-

toms are swollen glands, severe aches, chills, and fever, followed by red spots that can cover the body. Despite its name, Rocky Mountain spotted fever now occurs most commonly on the East Coast. North Carolina and Long Island are hot spots for the fever, and Connecticut averages a case or two each year.

Thus, when entomologists began to search for the tick suspected of causing Lyme arthritis, they were not searching in complete blindness. Some laboratories, the Agricultural Experiment Station was one, already had been sampling tick populations and had collected thousands of blood samples from animals and birds bitten by ticks. And there was no trouble finding ticks. A common method was to "flag" them. A field worker would go into a fertile tick area—some low-lying, moist place with a lot of undergrowth, perhaps close to a field or an animal track—and drag a foot-square flannel cloth through the brush. Ticks also were taken from woodland animals. Most animals were trapped alive, anesthetized, inspected, and released, explained Dr. Louis Magnarelli. Magnarelli, along with Dr. John Anderson, his senior at the experiment station, is a leading expert on the relationship of ticks and animals. Peanut butter and seeds were good bait for mice, while raccoons were attracted to sardines. Only deer were not trapped. To examine them, scientists stationed themselves at state deer-check stations during hunting season.

The prime suspect was a tick of the *Ixodes* genus, probably, *Ixodes scapularis*, a tick turned in by one of Steere's patients. Commonly known as the deer tick, *I. scapularis* is a smallish tick found primarily in the South. But it also seemed to be quite common in the Elizabeth Islands below Cape Cod, and it was certainly common in Lyme, Old Lyme, and East Haddam. It was incriminating that a Yale epidemiology team found the *I. scapularis* population in those east bank towns to be 12 to 16 times higher than in towns on the opposite bank of the Connecticut River. There wasn't much Lyme arthritis on the west bank, either.

The early indictment of *I. scapularis* proved to be a case of mistaken identity, however. In 1979, Dr. Andrew Spielman, a tropical diseases expert at Harvard, published research showing that the Lyme tick actually was a member of a less well-known *Ixodes* genus that apparently had staged an astounding comeback from the brink of extinction.

Spielman for some years had been studying ticks on Nantucket, where he had encountered a couple of cases of babesiosis, a malaria-like disease also spread by ticks. As part of his research, he had begun to breed the *I. scapularis* ticks he thought were at fault. To his surprise, Spielman discovered that the larvae hatched from the *I. scapularis* eggs looked like the larvae of *Ixodes muris*, the mouse tick. On closer examination, he decided the tick was neither *I. scapularis* nor *I. muris*, but a separate species. He named it *Ixodes dammini* after Gustave Dammin, a revered Harvard pathologist.

"I honored him," said Spielman, who added he himself was pleased to have had a lizard and a snake named

after him.

Ixodes dammini soon also was designated a deer tick. The ordinary white-tailed deer, it turned out, appeared to play a crucial role in the life cycle of *I. dammini*.

The species, like most other tick species, goes through three metamorphoses. Eggs, laid the previous fall and winter on the ground or on low bushes, hatch into larvae in spring. The larvae, which have only six legs and are so tiny they are almost invisible to the naked eye, are not particularly mobile. They may move a short distance to position themselves for the passage of a small animal, very often the white-footed mouse. As the animal brushes by, the larvae climb on for what is the first of only three "blood meals" the tick will eat in its life.

If it attaches, the larva engorges itself with its host's blood and falls back to the ground. In a few weeks, it emerges as a nymph, an eight-legged creature, not much larger than a period on this page, with a dangerously eclectic appetite. The nymphal deer tick, it turns out, is one of the few ticks that would just as soon dine on a human being as on its more traditional animal hosts such as mice, chipmunks, raccoons, and birds. The nymph is drawn to warm, soft places on the body; the neck, the underarm, the groin, the back of the knee. No matter where the nymph gets its blood, however, the end result is the same. It engorges and after a few days drops to the ground.

Though nymphs can begin to appear as early as April, their numbers peak in midsummer, when, unfortunately, humans are most likely to be tramping around in the woods. By fall most nymphs will have molted into adult ticks. The adults, which are slightly larger, about the size of a lower case "o" on this page, also may bite a human being, but their preferred host seems to be the deer. It is from the deer that the adult tick commonly takes its last and most important blood meal. While the tick can survive weeks and perhaps months between meals, it must eat before it can lay its eggs. Often, the deer even becomes the ticks' mating ground.

* * *

All the research devoted to the deer tick was of little public consequence, however, without hard evidence linking it with the disease afflicting people in the Lyme area. There, more people were falling ill each summer. By the time Spielman's paper on the new tick species was published, the ailment's name had been changed from Lyme arthritis to Lyme disease. Steere at Yale had followed patients long enough to determine that arthritis appeared to be just the final, and usually most severe, stage of the disease.

Steere also had realized that he was probably dealing with a bacterial disease, rather than a viral disease, as he initially thought. William Mast and William Burrows, the Navy doctors who had noticed the ECM rash back in 1975, were seeing more cases and favored treating them with antibiotics. In 1977, Steere and his colleagues tried antibiotics on all their cases. The result was not a miracle cure, but when they temporarily abandoned the antibio-

tic treatment in 1978, patients worsened. Ultimately, the key to the antibiotic treatment proved to be dosage and duration. (Anne Mensch never had a recurrence of the disease probably because the very first doctor who saw her, though he misdiagnosed her case, prescribed the right treatment: antibiotics given intravenously. It still is the preferred treatment for advanced cases of Lyme disease. Polly Murray thinks frequent doses of penicillin she took during her years of illness failed to cure her because they were too small or abbreviated.) The discovery that antibiotics worked against Lyme disease, however, gave little hint of what bacteria caused it.

Then in 1981, what scientists like to call serendipity provided the answer, though it was serendipity abetted by the world's leading authority on ticks. He was Dr. Willy Burgdorfer of the federal government's Rocky Mountain Laboratories in Montana, established 50 years ago to study Rocky Mountain spotted fever. At the time the deer tick was being studied so closely for its link with Lyme disease, Burgdorfer was collaborating with a team of New York Health Department scientists led by Dr. Jorge Benach who were searching for the cause of spotted fever on Shelter Island, a small island at the eastern tip of Long Island. Benach sent Burgdorfer a batch of deer ticks to be dissected and examined for traces of *Rickettsia rickettsii*, the spotted fever bacteria.

"Tick surgery is what we do, and what I've done for the last 30 years or so, ever since I started in this game," said Burgdorfer. "You take the tick and fix its legs in paraffin on a plate and when the paraffin cools...you take an eye scalpel [the sort used by eye surgeons] and cut..."

In searching for rickettsiae, Burgdorfer amputated the ticks' lower legs, took a sample of the blood that oozed out and prepared it for a microscope slide. When he looked at the blood of the Shelter Island ticks, Burgdorfer saw no rickettsiae, but in two ticks he saw tiny, worm-like organisms called nematodes. Out of curiosity, he cut the ticks open to look for further evidence of the worms. Instead he found an unfamiliar bacteria of the spiral-shaped sort known as a spirochete. Ultimately, he found the spirochete in more than half the ticks from Shelter Island. The way Burgdorfer told it, it was easy for him to put two and two together.

He knew that Shelter Island was Lyme disease territory, he knew about the rash, and he knew that decades before in Europe there had been an unsuccessful attempt to show that a spirochete from the sheep tick was responsible for ECM. Burgdorfer was familiar with the European research because he had been educated there. He was a native Swiss who had done his thesis on spirochetes at the renowned Swiss Tropical Institute.

"I knew the organism; I knew the literature," Burgdorfer said. "This is something Americans don't like to admit—Lyme disease is nothing new." (He later qualified his remark to mean that while some of its symptoms were known, the recognition of a whole range of symptoms as part of one disease was a discovery.)

Burgdorfer's own discovery of the spirochete was hardly automatic. Most others searching for the Lyme

disease agent, suspecting a virus, had bred the disease in laboratory animals and examined infected tissue. Burgdorfer attacked the tick directly and examined fluid loaded with living organisms under a dark field microscope. What he saw was not a detailed portrait of a spirochete, but a crowded pond where blurred, reflected images of certain of the inhabitants suggested by their shape and size and movement that they might be spirochetes. Only someone with Burgdorfer's "eye" would have thought them significant.

Once the specific bacteria had been identified, however, it was relatively simple to test whether it was in fact the Lyme disease agent. A strong case was made when a culture containing the spirochete provoked a reaction in blood specimens from Lyme disease victims provided by Benach's team. This case became ironclad some months later when Steere's group and Benach's group both reported finding the actual spirochete in Lyme disease victims.

Their findings, which solved the last of the original mysteries of the disease that was noticed because two mothers complained, were published in 1983. That same year at Yale, the first international symposium on Lyme disease was convened. The second symposium on Lyme disease was held last fall in Vienna, where papers representing the work of scores of different teams of scientists were read.

Allen Steere and his associates reported research that extended the list of symptoms associated with Lyme disease and noted that some of them can occur years after the disease's onset. "It's somewhat like syphilis in that respect," said Steere. "It can be quiescent for years." Indeed, Andrew Pachner, a neurologist working with Steere, encountered a case of dementia-insanity caused by the Lyme disease spirochete. (In fact, it is also a spirochete that causes syphilis, which has been called "the great imitator" of diseases. Lyme disease, also is an imitator and, as with syphilis, its symptoms can appear after many years.) Last year Steere and his supervisor Malawista went to Australia to accept the prestigious Ciba-Geigy Rheumatology prize worth \$27,000. "There are few examples in modern times of a single team accomplishing so much in such an elegant way," said one of the scientists who conferred the award.

Among several papers presented by Benach and his associates at the New York State Health Department, one noted that Lyme disease cases in New York had doubled since 1982 and declared that the disease "was a significant and expanding public health problem." Another reported on how the spirochete works in people. A case has been reported of a woman who went blind in one eye when the spirochete stopped there. At least one death has been connected to Lyme disease, that of a man whose heart had a spirochetal inflammation.

Lyme disease is not regarded as a life-threatening disease, however. Indeed, it is easily cured by moderate doses of antibiotics if the victim is treated soon enough. Yet it is regarded as a serious health problem because later symptoms, including arthritis, can be debilitating

and because the disease is so widespread.

* * *

Lyme disease is really an international disease. It has been reported on three continents. In Europe, a spirochete taken from the sheep tick was found to be nearly identical to the Lyme spirochete, and the slight differences are thought to account for the milder form of the disease there. In this country, the disease has been reported in more than 32 states, but is concentrated in seven: Wisconsin, Minnesota, New Jersey, New York, Massachusetts, Rhode Island, and Connecticut.

Of the nearly 1,500 cases reported in 1984 (complete figures for 1985 are not available), about 1,000 were split between New York and Connecticut, with most of the cases occurring in Westchester County and in the original towns on the east bank of the Connecticut River. For 1985, the Connecticut Department of Health Services expects to report almost double the 503 cases of the previous year. In Old Lyme, Dr. Gregory Kundrat, a family practitioner, said his office alone saw 112 patients with Lyme disease last summer. By early April 1986, he already had treated a dozen or so tick bites, even though the nymphal deer ticks that are the main carriers of Lyme disease will not reach their peak numbers until summer. Kundrat said it has become a bedtime routine among the families he sees to inspect their children for ticks.

The apparent doubling of Lyme disease cases between 1984 and 1985 does not prove it is twice as prevalent. At least a portion of the increase can be attributed to growing awareness of the disease. But the tick and the disease are spreading and, unfortunately, despite all the publicity about Lyme disease, it still is misdiagnosed in areas where the tick and the spirochete are newcomers. (Spielman of Harvard realizes now he saw numerous cases of the disease while doing his tick research but failed to recognize it because the geography was wrong. "I thought, if it wasn't in Lyme, it couldn't be Lyme disease," he said.) Lyme disease already has displaced spotted fever as the most common tick-borne illness in the United States.

In Connecticut, efforts to control the disease are mainly educational. The health department has concentrated on alerting doctors to it, while the Connecticut Arthritis Foundation plans to distribute 50,000 brochures (five times as many as last year) describing the symptoms, showing a picture of the rash, and explaining how to avoid tick bites.

Nothing is being done to eradicate the tick, because

the consensus is that not much can be done. Pesticides strong enough to kill the tick probably would pose a greater hazard than the tick itself. What's more, Magnarelli and Anderson of the Connecticut Agricultural Experimental Station have found evidence that mosquitoes and other biting insects may now be spreading the disease, though the tick is still the main carrier. An alternate control, killing deer and thus depriving ticks of their most crucial food source, has not been seriously considered because it is thought the tick would switch to other hosts. "Manipulation" of the deer populations, however, is being tried in other states. If the ticks cannot be eradicated, the only remaining preventive measures are avoidance or a vaccine. One has been developed in the lab of Dr. Russell Johnson at the University of Minnesota, but it has yet to be tested on humans. The lab is the same one that confirmed the Lyme spirochete was a new species, naming it *Borrelia burgdorferi* after its discoverer.

Spielman has become somewhat controversial for emphasizing the connection between tick and deer. "Listen. I'm a real naturalist," he said. "I'm a herdwatcher, a collector and observer of insects. The cause of the problem is deer. Whether removing them will solve the problem is another question."

Spielman has conjectured the tick probably was isolated on a few islands where the deer population had remained unnaturally large. Unlikely as it sounds, deer were much less common earlier this century when much of their habitat, brushy, wooded areas dotted with clearings, was swept away by farmers. As farming declined, the woods crept back, and the deer returned. So, probably, did the tick.

Indeed, Spielman thinks the tick may have survived only on Naushon Island, which lies a few miles off the south coast of Cape Cod. Specimens of the deer tick taken from Naushon in the 1920s have since been found stored in Harvard laboratories. It happens that the island for centuries was a hunting preserve. At the time of the Revolution, Hessian mercenaries poached deer there and, later, Presidents Ulysses S. Grant and Teddy Roosevelt hunted there. The tick may have been carried from the island by birds and dropped where its favorite food host was again suddenly plentiful.

There is one other crucial component of Lyme disease ecology besides the spirochete, the tick, and the deer. This other species also prefers to live quietly on abandoned agricultural land. It is called the suburbanite. As many scientists and health officials are fond of pointing out, 2-acre zoning is perfect for Lyme disease.

Editorials

Guest Editorial

A Message to Physicians

The doctors of Connecticut, along with those of nearby coastal states where Lyme disease is endemic, are on the "front line" of diagnosing and treating this illness. I would urge physicians all over the state to keep up with the literature on Lyme disease, because people can acquire the infection both when traveling or in their own hometown. They can present with symptoms at any time of the year, although beginning stages are most often in the spring, summer, and fall. Doctors in every specialty should be aware of how this disease affects their patients. General practitioners, pediatricians, rheumatologists, neurologists, and orthopedists probably see the most Lyme disease. Specialties such as dermatology, cardiology, ophthalmology, dentistry, otolaryngology, podiatry, obstetrics and gynecology, urology, psychiatry, and gastroenterology all have the possibility of seeing patients in any phase of the disease. Obstetricians especially should recognize the symptoms, given the danger of Lyme disease in a pregnant woman, and its possible effect on the fetus.

Because of the high number of cases of the disease in the spring and summer, the peak tourist months, emergency rooms and clinics should be particularly on the alert, as vacationers are more likely to go to these facilities with early symptoms.

Those who treat patients with Lyme disease should report their findings to the state in order that the true incidence of the disease can be known, and its geographic spread described. Because of the relapsing nature of Lyme disease, reporting and monitoring are crucial. If done conscientiously, they could aid significantly in describing the way the disease manifests itself. Often it is not a clear cut, self-limited disease; instead it can become a chronic, complicated, long-term disease process. Perhaps doctors could share information with their colleagues as well as educate medical students and health care workers. Ideally, within every state, there would be a designated researcher on Lyme disease in each specialty who would gather information and become an advisor to other professionals in their particular field.

A fuller understanding of the disease will come from in depth, longitudinal study of endemic areas where there have been the highest number of cases. Having heard so many stories of ongoing complications, I know that this disease is a constant threat to the health and stability of an ever increasing number of families. There are symptoms of extreme fatigue, sleep and behavior disturbances, rashes, and joint and muscle pain associated with this infection. Every year there are those who are newly

infected, and their numbers are added to the growing number of earlier cases that have either not yet been properly diagnosed, or that have been treated and yet continue to have problems. In addition, there are reinfections.

Some physicians may categorize some of these patients as "chronic complainers." Granted, there may be a few psychosomatics among the patients who wonder whether they have chronic Lyme disease, but it is possible that the vast majority of these "difficult to diagnose" patients, especially in highly endemic areas, may indeed have tick-related illness. It is my feeling that borrelia spirochetes may turn out to be a triggering factor in many diseases that have been described for many years, but for which a cause has not been found. I am hopeful that future research will uncover the answers to many of these enigmas.

Since the test for Lyme disease is not fool proof, and the diagnosis difficult due to the multisystemic nature of the illness, it is not surprising that victims often feel despair, confusion, and in need of support. If, at present, they don't have a diagnosable disease, what do they have? Has treatment worked? What are the recurrence rates? Reinfection rates? Is an individual's immune system weakened by the disease, causing a susceptibility to other illnesses? Is there a suspiciously high incidence of other diseases, in endemic areas, diseases that could be either misdiagnosed Lyme disease or illnesses triggered by a former Lyme disease infection (e.g. chronic fatigue syndrome)?

Many patients who at one time were treated for Lyme disease, have found out later, when they are experiencing the same symptoms, that they now test negative, and it is difficult for them to get retreated. Perhaps the present medications are aborting the antibody response, but are not in all cases destroying all of the spirochetes, some of which have managed to hide out in certain areas of the body. After a while, the spirochetes again reproduce to a new level and cause further symptoms. Perhaps reinfection with other strains of borrelia that would not react to the present tests may be the problem. Perhaps an, as yet, unidentified germ might also be transmitted by the tick in some cases.

Tremendous progress has been made worldwide since October 1975 and the initiation of the study of the "Mysterious Disease" first described in the Lyme area of our state. I am hopeful that with the cooperation of doctors everywhere this progress will accelerate.

Polly Murray

Lyme, CT

Polly Murray has dealt with Lyme disease on a personal, family, and community basis for over twenty years. In December 1988 she was given a special award by the National Institute of Allergy and Infectious Diseases for her dedication and contributions to the identification of Lyme disease as a new clinical entity.

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Sharing the Task of Lyme Disease Public Education

How do we spread the word about a new disease without spreading fear of the disease? And how do we lower expectations for final solutions when science does not yet have all the answers?

People responsible for public health education programs deliberate long and hard over the information supplied by health professionals and scientists. Their general goals are to help people recognize the symptoms of disease and to act to prevent illness or harm. Too little said may make the disease unnecessarily mysterious. Too much said may overstep what is known about the disease.

With Lyme disease, over the past 10 to 12 years, there has not been a comfortable middle ground. In the absence of scientific data, some patients have created their own answers. Not enough certainty in doctors' diagnoses has led to anxiety for many patients. Some have turned to old wives' tales, born again when medicine does not have the answers.

The public education messages about Lyme disease have evolved with the progress of science. In the early years, few people knew that their symptoms could be those of Lyme disease. In 1980, the need for antibiotic treatment for early Lyme disease was first reported.¹ The need to treat some cases of Lyme arthritis with intravenous penicillin therapy did not become part of the public health message until 1985.²

With the progress of science, even the name of the disease has evolved. At first, the disease was called "Lyme arthritis." Then it was called "Lyme disease," as additional manifestations of the disease became known. With the discovery of the infectious agent, many, especially in Europe, have chosen to call the disease "Lyme borreliosis."

Public education materials on Lyme disease were made available in 1982 by the Arthritis Foundation in Connecticut. The Foundation distributed 5,000 of its brochures between May 1982 and February 1983. Most of those were posted or distributed in doctors' offices, schools, and libraries in the southeastern and south central parts of the state. Each year after that, the brochure was revised to include the newest scientific and medical findings. The quantity of printed copies doubled, tripled, and quadrupled. In 1988 more than 200,000 printed pieces were distributed by the Foundation and the Connecticut Department of Health Services.

The Pfizer Corporation, which underwrote the first brochure for the Foundation, developed its own in 1986. Pfizer distributed 10,000 to Connecticut doctors that year. More than 25,000 brochures in 1987 and more than 300,000 brochures in 1988 were sent by Pfizer to doctors, health departments, and outdoor recreational facilities throughout the country.

People learned about Lyme disease from television, radio, newspapers, and printed materials; from programs in schools and community centers; and from their friends. Correspondingly, the number of visits to doctor's offices,

walk-in centers, and emergency departments by people with symptoms of Lyme disease increased dramatically.

With increased public awareness came demands for a solution to the problem of Lyme disease. These demands, which quickly outpaced the normal course of scientific discovery, helped to politicize Lyme disease. People mobilized to "find the culprit." The *Ixodes dammini* tick became secondary; the primary culprit was anyone who would not make the problem go away.

It is common now for scientists to appear together on the conference circuit, before television cameras, and at press conferences to discuss interesting hypotheses. Generally, people in the media inform responsibly, but fine distinctions are often lost in these media discussions. The public does not always perceive a difference between what is proposed as a question and what is confirmed as fact. This phenomenon of "science by media" keeps the public aware of the disease but not educated about it. To improve the reporting of science, scientists must become better at clearly delineating what is being questioned in research and what has been proven, and reporters must become better at discerning scientific fact from speculation.

An example of "science by media" occurred in March 1989 following a conference of Lyme disease researchers in Philadelphia. A researcher reported that she had recently isolated from human urine what were believed to be the spirochetes that cause Lyme disease. A writer from one of Connecticut's daily newspapers correctly reported the story, making clear that further research is needed (*The Day*; New London, CT; March 19, 1989). The writer also reported the following speculation: "The finding raises the question of whether Lyme disease can be transmitted venereally, because the spirochete might be in the urinary tract tissues..." Stories about this report, published by other newspapers, announced that Lyme disease may be a "sexually transmitted disease."

Part of the public health education problem is that the public remains largely ignorant of the process through which scientific "miracles" must go. The scientific method is a necessarily cautious process, and peer review of scientific findings is a necessary part of the process. Teaching the public about the scientific process is possible, and should be a priority for basic scientists, health professionals, and public health educators.

The rapid pace of Lyme disease research between the identification of the disease in 1975 and the unraveling of its ecology, transmission, and treatment was stunning. This same pace cannot be expected of science as it attempts to answer the complex questions about Lyme disease that confront investigators today.

Nancy L. Considine

Marlborough, CT

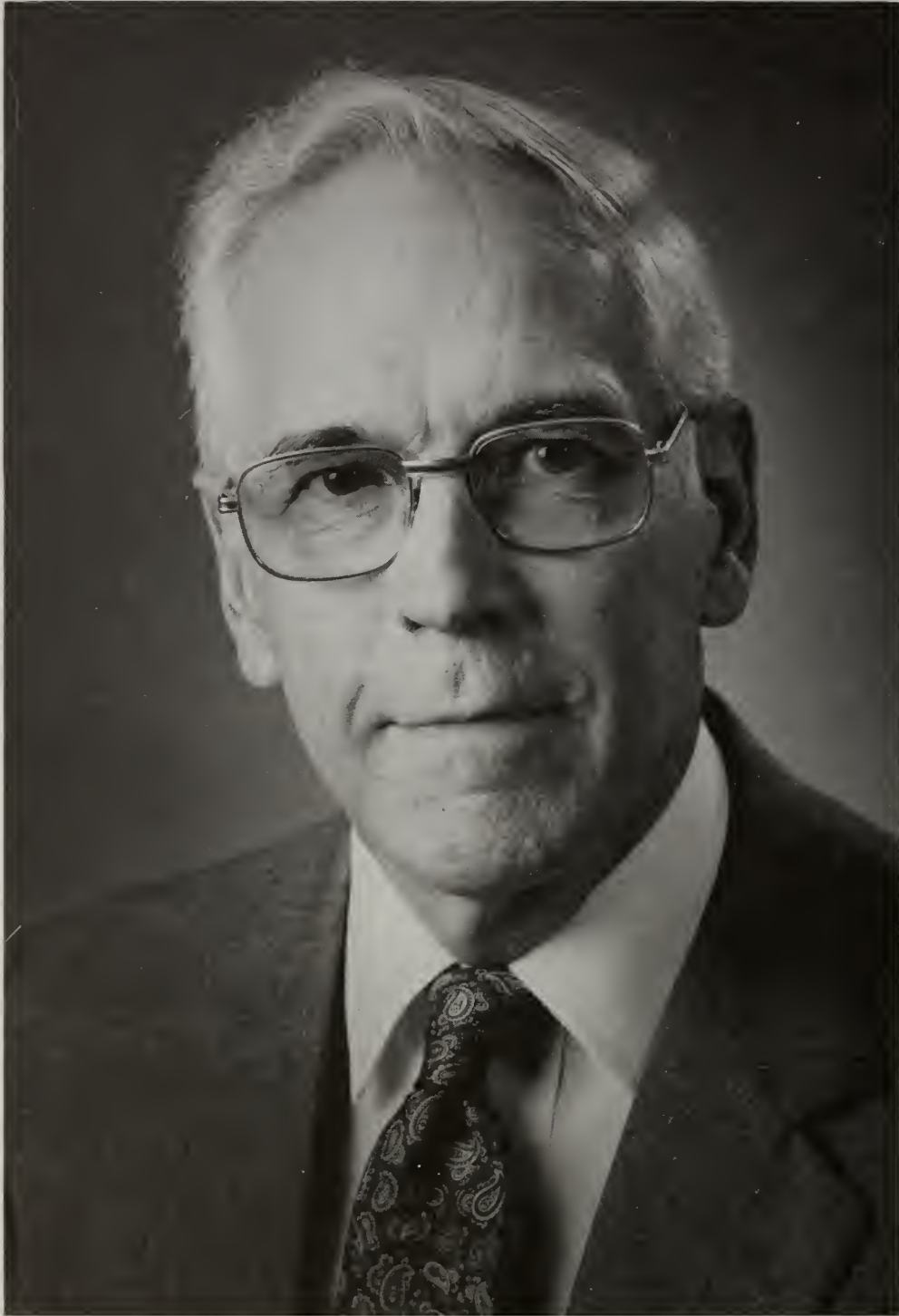
Nancy L. Considine, formerly with the Arthritis Foundation in Connecticut, developed many of the materials for public education programs on Lyme disease between 1982 and 1988.

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ROGER S. BECK, M.D.
President

The Year Ahead

As we look ahead to the coming year the challenges are many and the issues formidable. Are they worse than usual? Probably every incoming president thinks so; but you be the judge of that.

The immediate challenge we face is the need among ourselves to develop a greater sense of common purpose—of unity, if you will. Powerful forces, external and internal, are pulling us apart when we need most to be together. The major issue for us now is the high cost of health care. Public opinion polls confirm it; the average citizen is convinced of it; the media publicize it; and politicians react to it. The federal government responds to it and uses the leverage of Medicare fee reimbursement to regulate us as practicing physicians and the threat of antitrust action to control us as organized groups. Managed health care systems, HMOs and PPOs, are changing the traditional relationships among patients, providers, and payors in an almost revolutionary way. National corporations, justifiably concerned about large and increasing health care costs, are becoming more involved. The Resource Based Relative Value Scale (RBRVS) threatens to split further primary care physicians and specialists as new payment schedules are developed. Change is upon us as practicing physicians and as a profession.

Our own internal problems are of no less concern as we prepare to meet these changes. To date, our protests as individuals and as a profession about some of these changes have been to little avail and identified as self-serving. It is time for us to become more effective participants in this change—to improve our image as a profession, to involve ourselves in the ongoing studies about the distribution and appropriateness of health care, and to work with business and political leaders as the future of medical and all health care is being determined. About 64% of the licensed physicians in Connecticut are members of CSMS and only 44% of those with the MD degree nationwide belong to the AMA. On the local level and across the nation many physicians depend on their specialty societies to represent their interests. Our effectiveness as a group is weakened by the lack of membership in organized medicine as reflected in these numbers and the fragmentation of membership into specialty societies.

How, then, can the CSMS meet the challenge of representing the physicians of Connecticut? Our goal must be to develop and nurture better communications and relationships among individual physicians and specialty groups. We must find the common ground and establish mutually acceptable objectives. Your concerns and needs must be the Society's agenda. If a sense of common purpose can be achieved, you can be more completely represented at the AMA by your five delegates as issues like health costs are discussed and at the state level by your elected officers. These are some of the local issues we must consider now.

LEGISLATION remains a priority issue. Strengthened by your support and aware of your objectives, your officers, CSMS staff, and our lobbyists, Sullivan and LeShane, will be better prepared to be constructive participants as the General Assembly and its committees consider many bills introduced each year related to health care. CSMS has monitored over 100 bills this Year.

The Public Health Committee has reported out a number of these bills which have been referred to other committees for further consideration or await action by the legislature. This is a first step and bills approved by the committee can be amended or bills defeated in committee can resurface later as amendments to unrelated pieces of legislation. The legislature has yet to vote on many health care related bills. Constant vigilance is mandatory. One must wonder about the process and ponder the significance of words written long ago by Leo Tolstoy that "government is an association of persons who do violence to the rest of us."

PEER REVIEW: By tradition peer review has been done voluntarily by members of the profession and done well. The confidentiality of Review Board deliberations has been protected by law from "civil action." It appears that this mantle of confidentiality is being threatened by a recent Superior Court Decision. By a two to one vote in the case of the *Department of Health Services v Kadish*, the Justices ruled that this represented an "administrative action" and, therefore, was not covered under the law. The State Supreme Court has been requested to review the decision and their reply is awaited.

AIDS: As this disease has spread, now almost in epidemic proportions, concern among health care workers about their own exposure has increased. A resolution *Mandatory HIV Testing in Hospitals* has been introduced for debate and action at the House of Delegates on 10 May 1989.

LYME DISEASE: Finally there is the issue of Lyme disease. If it were not for AIDS, Lyme disease might be considered the most important new infectious disease in Connecticut. This special issue serves to emphasize the importance of this disease in our state.

Roger S. Beck, M.D.,
President



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Connecticut's Epidemics

ROBERT U. MASSEY, M.D.

*And so each place
Will bring to various parts and limbs its meed
Of Bane, whereof the divers airs are cause.
—Lucretius*

Diseases have come, lingered, changed, and even gone during the brief 6,000 years of our history; this generation has seen at least three come and one go: AIDS, Legionnaires' disease, and Lyme disease are apparently new, and small pox, thanks to the vaccine introduced by an English country doctor 193 years ago, is unquestionably gone.

Following Jenner's vaccination, aseptic surgery, serum therapy, salvarsan, the sulfonamides in the 1930s, penicillin, streptomycin, and the tetracyclines in the 1940s, isoniazid and poliomyelitis vaccine in the 1950s, our optimism that our high technology would in the end triumph over disease was unbounded. Even cancer, with hints that viruses were behind it all, seemed likely to yield before the century was out. Rheumatic fever, for reasons not entirely clear, appeared until recently to have fled the temperate zone; the incidence of heart disease and stroke was declining, and anyway arteries were fixable and organs transplantable; there remained some chronic diseases like arthritis, schizophrenia, and dementia that were about where they had always been, but they too would fall.

Then came Lyme disease, followed by Legionnaires'

disease, and before we could pay much attention to either, the acquired immunodeficiency syndrome, and we seemed to be starting all over with our ancient enemy just when we thought we had confined and hidden him behind hospital and nursing home walls. Fifth-century Athens and 14th-century Europe had been safely locked in the deep past, and the pandemic of 1918 had been lost in the shadow of the War's end and trivialized by its name.

How could "flu" be terribly serious? Only those over 75 can remember it now. But before that epidemic had burned itself out more than 15 million were dead worldwide, almost twice the 8.5 million lost in the war that was just ending. The disease probably appeared first in China in February 1918; by March it was in the United States, and in New London by September. That October alone, Connecticut had 1,700 deaths from influenza in a population of 1.4 million, and more than 33,000 cases were reported.¹ The case fatality rate was running between 6% and 12%, with most in the 20 to 40 age group. In 1917 there had been 6,003 deaths in Connecticut from all causes; in 1918, 14,057.

The throat distemper of 1735-40 was too far in the past to worry anyone now, but it had swept through Connecticut taking one out of three children under ten. It may have carried a case fatality rate of 60%; from the symp-

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toms described and its high mortality, diphtheria seems to be the best guess.²

As you have read in this issue of *Connecticut Medicine* Lyme disease appeared first in Connecticut in 1975, and by 1982 a treponema-like spirochete presumed to be the causative agent was isolated from the tick vector, *Ixodes dammini*. Last year there may have been as many as 3,500 new cases in the state. Although the disease had apparently been seen in Sweden as early as 1909, it was new to the United States, and is now number one among tick-transmitted diseases.

Microorganisms do not have to be smart to outwit us; with generations measured in minutes and hours rather than years, evolution moves faster for them, and they adapt to our strategies. Fortunately we had the therapy for Lyme disease in hand and used it to test assumptions even before Willy Burgdorfer found the spirochetes; now, though the clinical syndromes involve multiple systems and are often atypical, we need only to think of the diagnosis. We were less well prepared for AIDS

when it appeared in 1981, and unraveling that tangle would have seemed hopeless had the disease shown up before the existence of human retroviruses was known, and before there was agreement about the function of T cells and B cells.

In neither instance did research move as quickly as the public had come to expect. New diseases evoke fears that spread and grow in ways more socially disruptive than the diseases themselves as long as questions hang unanswered in the air. Yet knowledge is built only upon knowledge, and even the remarkable progress of our late 20th-century biomedical science is limited by the experience and imagination of investigators, the techniques available to them, and by luck.

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50 Years Ago

From the *Journal of the Connecticut State Medical Society* June 1939

State of Connecticut
DEPARTMENT OF HEALTH
Hartford

April 5, 1939

Editor,

Journal of the Conn. State Medical Society, Hartford, CT

My dear Sir:

Here is something on "Sulfapyridine in Pneumonia" in case you want to use it in the Journal. It appeared to me that the opinion of the advisory committee on pneumonia control of the New York State Department of Health might be worth sending out to our own physicians.

Sincerely yours,
Millard Knowlton, *Director*

CHEMOTHERAPY IN PNEUMONIA

Because of the encouraging reports of the use of sulfapyridine in the treatment of pneumonia, the Advisory Committee on Pneumonia Control of the New York State Department of Health met in a special session on February 17, 1939, and, after considering available data concerning the toxicity of this drug and the evidence as to its efficacy in the treatment of pneumonia, adopted the following resolution:

"Be It Resolved That,

"The Advisory Committee on Pneumonia Control to the New York State Department of Health, after weighing the available evidence, is of the opinion that sulfapyri-

dine has a beneficial effect in the treatment of some patients ill with pneumococcal pneumonia.

"It is further the opinion of this Committee that the efficacy of antipneumococcus horse and rabbit sera for the treatment of certain types of pneumococcal pneumonia has been established. The evidence does not justify the substitution of sulfapyridine for serum therapy in all patients with pneumococcal pneumonia. Further investigations are necessary before it will be possible to state which patients should be treated with serum and which with sulfapyridine. Laboratory studies, including sputum typing and blood culture, are necessary for rational therapy and for the determination of the efficacy of any form of treatment.

"It is further the opinion of this Committee that sulfapyridine may be administered under competent supervision with reasonable safety in spite of the frequent evidence of toxicity.

"It is further the opinion of this Committee that the hazards incident to the administration of this drug can be lessened by careful clinical observations and by laboratory examinations which give warning of the more dangerous toxic effects which occasionally occur.

It is therefore the opinion of this Committee that, with the restrictions and precautions above mentioned, sulfapyridine should be released for use by physicians or on physicians' prescriptions."

—*Bulletin New York State Department of Health*

Legal Implications of Uncertainty in Lyme Disease

NANCY WILLIAMS, R.N., J.D., LL.M.

THE practice of medicine is beset by great uncertainty. Indeed, advances in medical knowledge notwithstanding, for a long time to come, if not forever, its practice will be accompanied by considerable ignorance. It is the legacy of science that scientific activity produces not only new knowledge but also new ignorance.¹

These words by Jay Katz have special significance for physicians in the context of Lyme disease, where the effort to diagnose and treat patients is complicated not only by the existence of uncertainty in medicine but also by a related uncertainty concerning the law.

First, there is a frustrating lack of reliable information concerning many aspects of the disease including specific symptomatology, diagnostic testing, treatment protocols, and the rate and effect of transmission from mother to fetus during pregnancy. Although early diagnosis and treatment are crucial to preventing serious and potentially permanent complications, early symptoms of this "great new imitator" can be misleading. To confirm a diagnosis, current testing for Lyme disease depends on antibody production that takes valuable time. If sufficient evidence exists to suspect Lyme disease, a quick medical response is indicated. However, in a significant number of cases, frightened patients present with vague, non-specific symptoms and no characteristic skin lesion, demanding immediate, aggressive antibiotic therapy. Treatment with relatively high doses of either of the two drugs of choice, penicillin or tetracycline, can produce serious negative consequences. Physicians caught in this dilemma find no medical consensus to direct them. Even state health departments are not uniform in their recommendations concerning early treatment prior to definitive test results or the development of characteristic symptoms. (The Connecticut Department of Health Services' position on this is to make no official recommendation either to treat or not to treat in these questionable cases. Other states have taken other positions.)

Besides uncertainty about the best medical protocol, physicians often fear vulnerability to a charge of negligence in either a treatment or a nontreatment situation should future complications arise. While research activity over time will eventually lessen the uncertainty related to medicine, strategies can be developed now to control for at least a portion of the legal uncertainty.

First, the physician must keep abreast of evolving information concerning diagnosis and treatment. The

law, should the question of negligence arise, would generally look to the medical profession itself for a determination of the appropriate standard of care. Although there has been a shift in defining the relevant community from the old locality rule to a more national standard, it is prudent for the physician to remain aware of evolving practice as reflected in his or her own geographic area as well as in the national literature.

In addition to understanding and practicing within the appropriate standard of care, the physician should ensure that the medical record reflects a reasonable basis for his or her professional judgement. This is important whether the decision is to initiate early treatment with antibiotics or to await a more definitive diagnosis. In considering alternative approaches, the physician should document evidence of the patient's informed consent. Providing the patient with accurate, up-to-date information on what is known about Lyme disease as well as about the areas of uncertainty that still exist can help to tailor more realistic patient expectations and decrease the likelihood of future legal entanglements. If problems do arise, the best defense for the physician, in the context of Lyme disease as in most other situations, is to be able to rely on a well-documented medical record that reflects a reasonable, patient-centered treatment plan.

With all of the questions that remain unanswered concerning Lyme disease, more than one approach could be medically reasonable and therefore legally justifiable. As data accumulate, more of a consensus will form. Still, the medical standard of care is rarely like a tightrope from which any slight deviation automatically spells medical (and legal) disaster. Rather, there is usually a margin of choice with room for the exercise of professional judgement and for reasonable minds to differ.

Unfortunately, there is no way to totally eliminate the existence of uncertainty. Still, as Katz suggests,

There is a bright side... Since doctors are now better situated than they ever have been to make distinctions between the known, the unknown, and the unknowable, they can be better aware of, and converse more knowledgeably with patients about, medicine's uncertainties.¹

Acknowledgement of the medical uncertainty associated with Lyme Disease can be the basis from which the wise physician endeavors to share the "burdens of decision"¹ with the well informed patient, thus providing better patient care and at the same time substantially diminishing his or her own future legal liability.

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Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

PRACTICING IN LYME DISEASE TERRITORY

To the Editor: We are writing to share our experiences acquired in a large pediatric practice located in the "heart" of Lyme disease territory, the Lower Connecticut River Valley.

The warmer season each year brings numerous calls each day which confirm the lay ignorance and confusion surrounding Lyme disease. This is reinforced by the multitude of discrepant (not necessarily incorrect) protocols followed by different practitioners and referral centers.

Therefore, our office has adopted the following protocol:

1. Any patient with a rash, sounding at all like erythema migrans (EM), is invited to the office. If the rash is confirmed as EM by the physician, a detailed exposure history is obtained, and the patient is treated orally with either tetracycline, amoxicillin, or erythromycin, depending on patient age and drug allergy history, if any.

Treatment is given for a minimum of 14 days. Lyme titers were obtained in earlier patients, but with close to 100% being within normal range (presumably due to the absence of antibody during the early stages of Lyme disease) this practice has not been continued. Recently, more sensitive tests are employed in some labs (see below) which may make early and perhaps convalescent titers more meaningful.

2. All patients with signs of inflammatory joint disease, are evaluated with a rheumatoid blood screen which always includes Lyme titers. Those with elevated titers are also treated orally, as above, although the length of treatment may be extended. Likewise, other patients with protracted fevers, significant headaches, Bell's palsy, etc. are also screened with Lyme titers and treated as indicated. We have not been aware of any cardiac involvement in our practice. Only once, has it been necessary for us to treat a patient with intravenous antibiotics (a child who failed oral antibiotic therapy for Bell's palsy due to Lyme disease).
3. We do not treat any patients prophylactically after a history of bites, nor do we treat any patients over the phone. We *do* treat if EM appears, and have not experienced any late manifestations following such treatment. We feel that to treat all people with with suspicious bites makes no better sense than to treat all children all winter in an attempt to prevent acute rheumatic fever.

Finally, it has been our experience that serologic examination has yielded widely variant results depending on the laboratory and the test performed. We, as well as others, have sent a divided sample to three different laboratories, and have received three different results: negative, positive, and equivocal. It becomes abundantly clear that a reproducible, acceptable test must be agreed upon as soon as possible. Until then, case reporting of Lyme disease is meaningless. An accurate test will also decrease the physician paranoia which results in overdiagnosing this highly emotionally charged syndrome, in order to avoid peer criticism for "missing" a case of Lyme disease.

Donald P. Buebendorf, M.D.
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ODE TO THAT DAMMINI IXODES

To the Editor: I am a pediatrician in East Lyme, CT. Lyme disease impacts my office on a daily basis during the height of the season.

It is routine for many physicians in the area to treat a tick bite on the day it occurs. It has been my practice not to treat at this point. To this date there has not been a single (ouch!) adverse consequence to this approach.

When a tick bite occurs, the tick should be saved and identified as a minimum criteria for antibiotic treatment. If the tick is a deer tick, parents are offered the option of therapy or encouraged to put out their antennae for any perceived signs of illness and call back directly. Essentially no parents choose treatment at this juncture. Parents are told that at least 30% of infections are occult. Parents are aware that many children would need a half dozen two-week courses of antibiotics each year if treatment was the norm. It should also be noted that each patient visit requires a great deal more time than it would if antibiotic therapy was automatic.

In my experience, the vast majority of deer tick bites do not result in transmission of Lyme disease. There are a few families in my practice whose children have had many bites each year, and for many years in a row their Lyme titers, done in the fall, remain negative.

At this point in the saga of Lyme disease, perhaps the biggest burden for the clairvoyant primary care doctor is to impart absolution for each of the myriad skin lesions that might represent a tick bite. A random summer skin lesion (not even known to be the consequence of a bite) and classic erythema migrans are oceans apart. The real challenge is to identify the unobtrusive blemishes that represent infection and are not readily identified as erythema migrans.

Charles H. Robinson, M.D.
East Lyme, CT

LYME DISEASE AND ANTIBIOTIC PROPHYLAXIS

To the Editor: It has been said that if we did not have the present AIDS epidemic, Lyme disease would be the most serious new infectious disease of the decade.

The spectrum of symptoms caused by Lyme disease now extends to almost all organ systems, from the central nervous system to the heart, and has reached out to the fetus of pregnant mothers infected with *Borrelia burgdorferi*. If the diagnosis is not made in the early stages when the memory of a tick bite is still fresh and a more or less typical rash is still visible, it becomes progressively more difficult to recognize and treat the disease. If the patient is also seronegative for antibody to *B. burgdorferi*, it can be very hard to identify the cause of the symptoms.

Intense research is going on all over the world concerning this disease. In spite of this, the situation is still very complicated. Vaccines are under development by both medical and veterinary researchers, but they are still several years away. What do we do in the meanwhile? Would it be prudent to use antibiotics prophylactically? Considering the potentially heavy toll of late Lyme disease, it would sound logical to try this. Of course, this would only benefit those people who know that they have been bitten by a tick.

In the recent study by Costello et al,¹ the authors concluded that, as always, clinical judgment should guide the decision to use antibiotics prophylactically. Let's face it, how much would it cost to treat the appropriate cases of tick bite with antibiotics compared to all the problems and expenses connected with a fullblown case of Lyme disease, which sometimes can even lead to permanent disability?

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A STUDY OF EARLY LYME DISEASE TREATMENT

To the Editor: It is well known that Lyme disease is a major health problem in Connecticut. What is not well known is the proper treatment for the disease. One hears of numerous treatment protocols.^{1,2,3} for Lyme disease in each of its various stages. Unfortunately, apart from the work of Steere⁴ and Neumann,⁵ there are no large clinical trials on the treatment of Lyme disease published in the medical literature.

The Family Practice Residency Program of Middlesex Memorial Hospital will be coordinating a prospective, partially-blinded clinical trial of early Lyme disease treatment. Study participants will include family physicians in private practice along the lower Connecticut River valley. This study is to begin in May 1989 and will be

enrolling patients for two years. The study will be comparing amoxicillin and doxycycline for both a 10 day and 21 day course of treatment.

Enrollment into the study will be limited to those patients who have early Lyme disease as determined by the presence of the typical rash of erythema migrans as determined by one of the study physicians. Exclusionary criteria are age less than eight years, pregnancy, a history of documented Lyme disease, or a previously positive serology for Lyme disease.

Any persons interested in learning more about the project or who wish to refer patients for enrollment into the study should contact the study coordinators at 344-6305.

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REINFECTION WITH *BORRELIA BURGDORFERI*

To the Editor: As part of a retrospective study of reported Lyme disease cases conducted by the Connecticut Department of Health Services in early 1987, an attempt was made to obtain information on 100 of the 342 persons with erythema migrans who were reported to the health department in 1984. Clinical information was obtained from the reporting physicians on 68 persons with erythema migrans. Eight (12%) of the 68 had had a second episode of physician diagnosed erythema migrans in either 1985 or 1986; these episodes occurred in June through October. Thirty-eight persons (56%) did not have a second episode, and the physician did not know if the patient had had a second episode in 22 (32%) cases.

Of the eight persons with a second episode of erythema migrans, all had received antibiotic treatment for at least 10 days for the initial episode; seven had been treated with tetracycline and one with erythromycin. Of the remaining 60 persons, 49 were treated with either tetracycline, penicillin, or erythromycin for at least 10 days; three persons were treated with other antibiotics; three received antibiotics for less than 10 days; two persons received no antibiotics; and treatment information was not available for three persons.

A second episode of erythema migrans may be due to reinfection with *Borrelia burgdorferi* or may be due to recurrence of the initial infection.¹⁻⁴ Reinfection with *B. burgdorferi* is likely if appropriate antibiotic treatment was given for the initial episode and if the second episode occurs during peak Lyme disease season from May through October in the year or subsequent years following the initial episode. Reinfection with *B. burgdorferi* can happen in subsequent summers because no long-lasting immunity seems to occur following erythema migrans that has been adequately treated.¹⁻³ A second episode of erythema migrans can be due to recurrence of the initial infection in persons who have not been treated or who have received inadequate treatment.^{3,4}

The eight persons in our study with second episodes of erythema migrans probably had been reinfected with *B. burgdorferi*; they had received appropriate antibiotic treatment for the initial episode and had their second episodes during peak Lyme disease season. The rate of reinfection (12%) in our study is similar to the rate found in a recent study of permanent residents of a coastal community in Massachusetts.⁵ During the period 1984 through 1987, five (12%) of 42 residents with erythema migrans were reinfected with *B. burgdorferi*; all five had received antibiotic therapy for their initial illness.

Antibiotic therapy early in the course of Lyme disease is effective in preventing the later complications of the disease.⁶ Our results combined with the results of Lastavica et al⁵ suggest that reinfection with *B. burgdorferi* can occur frequently among persons who receive such treatment. We recommend that when treating early Lyme disease, physicians should also routinely counsel their patients with erythema migrans about the danger of reacquiring Lyme disease, especially in endemic areas.

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LYME DISEASE CLINICAL TRIAL

To the Editor: We are writing to inform your readers of a study that we will be conducting this summer. The study is a double-blind, randomized clinical trial of amoxicillin v placebo to prevent Lyme disease in children and adults who have been bitten by a deer tick. Blood will be obtained at the time of enrollment and again in six weeks and several months later for the determination of antibodies to *Borrelia burgdorferi* at the end of the season. Patients who develop symptoms of Lyme disease will be referred to their own physicians for treatment (and the drug code will be broken). The medication will be given and antibody studies performed without charge to the patient. We will have a "Lyme Disease Study Center" in the Madison area where patients will be enrolled in the study. For further information contact: Eugene D. Shapiro, M.D. at 785-4518 or Michael A. Gerber, M.D. at 679-2221.

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NEW LYME DISEASE CLINIC AT UNIVERSITY OF CONNECTICUT HEALTH CENTER

To the Editor: A new multidisciplinary clinic has been started at the University of Connecticut Health Center to provide both referral and primary services for patients with known or suspected Lyme disease. The clinic, under the direction of Dr. Sam T. Donta (internal medicine) and Dr. Michael A. Gerber (pediatrics), will also be served by faculty in neurology, laboratory medicine, and rheumatology. Working together, the group hopes to address issues concerning the laboratory diagnosis, treatment, pathogenesis, and prevention of Lyme disease. For further information, call 679-3245.

Sam T. Donta, M.D.

University of Connecticut School of Medicine
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BOOK REVIEW

Lyme Disease and Related Disorders

Editors: Jorge L. Benach and Edward M. Bosler. Volume 539, *Annals of the New York Academy of Sciences*, 1988, 513 pp. \$128.00 (cloth).

This volume on Lyme disease is another of a series of valuable contributions by the New York Academy of Sciences. It represents a compilation of papers and posters presented at the International Conference on Lyme Disease and Related Disorders in New York City September 14-16, 1987, co-sponsored by the New York Academy of Sciences and the State of New York Department of Health. Although one might be concerned about being out-of-date in a relatively new and quickly evolving field, much of the information still seems timely 18 months or so after the conference.

Because of the format of the conference, the sections are organized much as they must have been during the conference. While still valuable in its individual contributions, this format is not as conducive to a review of the topic as one better organized along classical textbook lines that progress from considerations of history, epidemiology, and etiology, to clinical, diagnosis, treatment, and prevention of disease.

For the person attending the conference, the volume serves as an excellent review of the sessions; for the person not present at the conference, the volume is a somewhat disorganized and cumbersome review of the subject.

The sections are divided into five parts, plus contributions from two poster sessions. Each of the five parts has an excellent brief introduction that is supposed to serve as a mini-review of the sessions as well; in this regard, a better summation following the individual contributions would have been more helpful. The five parts, in order, are I: Clinical Manifestations and Pathology, II: Microbiology and Antibody Response, III: Ecology, IV: Veterinary, Animal Models, and Epidemiology, and V: Treatment. These are followed by Poster Session I: Basic Research Poster Papers, and Poster Session II: Veterinary, Clinical, and Epidemiological Poster Papers. From an organizational point of view, much could have been gained from better consolidation of the different topics, including incorporation of the poster papers into their appropriate sections. For example, "The role of interleukin-1 in the pathogenesis of Lyme disease," "The pathogenesis of Lyme arthritis," "Specific immune responses in Lyme borreliosis," and "Modulation of natural killer cell activity by *Borrelia burgdorferi*" are contributions appearing in Part I that would better fit in Part II or Part IV. And, "Prospects for suppressing transmission of Lyme disease" that appears in Part III (Ecology) would probably better fit in Part V. The strengths of Part I lie in the clinical and pathological descriptions of nervous system abnormalities associated with Lyme disease, not so surprising because of the session's modera-

tor, Dr. Louis Reik. Dr. Steere's contribution on the pathogenesis of Lyme arthritis in this same section is a concise review of the topic, somewhat of an editorial, but not going into the type of depth that typifies his many journal contributions on the subject.

Notable in Part II are Dr. Alan Barbour's valuable contributions on antigenic variability and information about the surface proteins of the etiologic agent. Dr. Magnarelli gives an excellent review of the serologic diagnosis of Lyme disease, emphasizing the many inherent problems and the need for better tests.

Parts III and IV also contain valuable information about the tick vectors, reservoirs, and epidemiology of the infection in animals and man. Part V on treatment is rather skimpy. The current consensus is that tetracycline is probably a more effective agent than penicillin for the treatment of arthritis, yet this aspect is not really discussed in this section. It might also have been important to emphasize the lack of effectiveness of erythromycin and the only partial efficacy of penicillin in other than early stages of the disease.

Missing from the reviews are discussions of differential diagnosis. Otherwise, this volume on Lyme disease has much to offer the interested reader. Unless a member of the New York Academy of Sciences however, it is difficult to recommend spending \$128.00 for it. One can find more comprehensive individual journal review articles.

Sam T. Donta, M.D.

Farmington, CT

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Dr. Holwick outside of hospital where she practices as a civilian traumatologist.



Dr. Holwick in operating room at Letterman Army Medical Center.

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General and Trauma Surgeon.
Captain, U.S. Army Reserve.

EDUCATION University of Southern California, B.S.
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Carcinogenesis, Mutagenesis, Impairment of Fertility — A two-year oral carcinogenicity study in rats with doses as high as 500 mg/kg/day (about 80 times the recommended daily therapeutic dose) showed no evidence of a carcinogenic effect. There was a dose-related increase in the density of enterochromaffin-like (ECL) cells in the gastric oxyntic mucosa. In a two-year study in mice, there was no evidence of a carcinogenic effect. However, hyperplastic nodules of the liver were increased in the high-dose males as compared with placebo. Female mice given the high dose of Axid (2,000 mg/kg/day, about 330 times the human dose) showed marginally statistically significant increases in hepatic carcinoma and hepatic nodular hyperplasia with no numerical increase seen in any of the other dose groups. The rate of hepatic carcinoma in the high-dose animals was within the historical control limits seen for the strain of mice used. The female mice were given a dose larger than the maximum tolerated dose, as indicated by excessive (30%) weight decrement as compared with concurrent controls and evidence of mild liver injury (transaminase elevations). The occurrence of a marginal finding at high dose only in animals given an excessive and somewhat hepatotoxic dose, with no evidence of a carcinogenic effect in rats, male mice, and female mice (given up to 360 mg/kg/day, about 60 times the human dose), and a negative mutagenicity battery are not considered evidence of a carcinogenic potential for Axid.

Axid was not mutagenic in a battery of tests performed to evaluate its potential genetic toxicity, including bacterial mutation tests, unscheduled DNA synthesis, sister chromatid exchange, mouse lymphoma assay, chromosome aberration tests, and a micronucleus test.

In a two-generation, perinatal and postnatal fertility study in rats, doses of nizatidine up to 650 mg/kg/day produced no adverse effects on the reproductive performance of parental animals or their progeny.

Pregnancy—Teratogenic Effects—Pregnancy Category C — Oral reproduction studies in rats at doses up to 300 times the human dose and in Dutch Belted rabbits at doses up to 55 times the human dose revealed no evidence of impaired fertility or teratogenic effect, but, at a dose equivalent to 300 times the human dose, treated rabbits had abortions, decreased number of live fetuses, and depressed fetal weights. On intravenous administration to pregnant New Zealand White rabbits, nizatidine at 20 mg/kg produced cardiac enlargement, coarctation of the aortic arch, and cutaneous edema in one fetus and at 50 mg/kg it produced ventricular anomaly, distended abdomen, spinal bifida, hydrocephaly, and enlarged heart in one fetus. There are, however, no adequate and well-controlled studies in pregnant women. It is also not known whether nizatidine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Nizatidine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers — Studies conducted in lactating women have shown that <0.1% of the administered oral dose of nizatidine is secreted in human milk in proportion to plasma concentrations. Caution should be exercised when administering nizatidine to a nursing mother.

Pediatric Use — Safety and effectiveness in children have not been established.

Use in Elderly Patients — Ulcer healing rates in elderly patients are similar to those in younger age groups. The incidence rates of adverse events and laboratory test abnormalities are also similar to those seen in other age groups. Age alone may not be an important factor in the disposition of nizatidine. Elderly patients may have reduced renal function.

Adverse Reactions: Clinical trials of nizatidine included almost 5,000 patients given nizatidine in studies of varying durations. Domestic placebo-controlled trials included over 1,900 patients given nizatidine and over 1,300 given placebo. Among reported adverse events in the domestic placebo-controlled trials, sweating (1.1% vs 0.2%), urticaria (0.5% vs <0.01%), and somnolence (2.4% vs 1.3%) were significantly more common in the nizatidine group. A variety of less common events was also reported; it was not possible to determine whether these were caused by nizatidine.

Hepatic — Hepatocellular injury, evidenced by elevated liver enzyme tests (SGOT [AST], SGPT [ALT], or alkaline phosphatase), occurred in some patients and was possibly or probably related to nizatidine. In some cases, there was marked elevation of SGOT, SGPT enzymes (greater than 500 IU/L) and, in a single instance, SGPT was greater than 2,000 IU/L. The overall rate of occurrences of elevated liver enzymes and elevations to three times the upper limit of normal, however, did not significantly differ from the rate of liver enzyme abnormalities in placebo-treated patients. All abnormalities were reversible after discontinuation of Axid.

Cardiovascular — In clinical pharmacology studies, short episodes of asymptomatic ventricular tachycardia occurred in two individuals administered Axid and in three untreated subjects.

CNS — Rare cases of reversible mental confusion have been reported.

Endocrine — Clinical pharmacology studies and controlled clinical trials showed no evidence of antiandrogenic activity due to Axid. Impotence and decreased libido were reported with equal frequency by patients who received Axid and by those given placebo. Rare reports of gynecomastia occurred.

Hematologic — Rare thrombocytopenia was reported in a patient who was treated with Axid and another H₂-receptor antagonist. On previous occasions, this patient had experienced thrombocytopenia while taking other drugs. Rare cases of thrombocytopenic purpura have been reported.

Integumental — Sweating and urticaria were reported significantly more frequently in nizatidine- than in placebo-treated patients. Rash and exfoliative dermatitis were also reported.

Hypersensitivity — As with other H₂-receptor antagonists, rare cases of anaphylaxis following administration of nizatidine have been reported. Because cross-sensitivity in this class of compounds has been observed, H₂-receptor antagonists should not be administered to individuals with a history of previous hypersensitivity to these agents. Rare episodes of hypersensitivity reactions (eg, bronchospasm, laryngeal edema, rash, and eosinophilia) have been reported.

Other — Hyperuricemia unassociated with gout or nephrolithiasis was reported. Eosinophilia, fever, and nausea related to nizatidine administration have been reported.

Overdosage: Overdoses of Axid have been reported rarely. The following is provided to serve as a guide should such an overdose be encountered.

Signs and Symptoms — There is little clinical experience with overdosage of Axid in humans. Test animals that received large doses of nizatidine have exhibited cholinergic-type effects, including lacrimation, salivation, emesis, miosis, and diarrhea. Single oral doses of 800 mg/kg in dogs and of 1,200 mg/kg in monkeys were not lethal. Intravenous median lethal doses in the rat and mouse were 301 mg/kg and 232 mg/kg respectively.

Treatment — To obtain up-to-date information about the treatment of overdose, a good resource is your certified regional Poison Control Center. Telephone numbers of certified poison control centers are listed in the Physicians' Desk Reference (PDR). In managing overdose, consider the possibility of multiple drug overdoses, interaction among drugs, and unusual drug kinetics in your patient.

If overdosage occurs, use of activated charcoal, emesis, or lavage should be considered along with clinical monitoring and supportive therapy. Renal dialysis for four to six hours increased plasma clearance.

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From the Executive Director's Office

SUMMARY OF PROCEEDINGS CSMS HOUSE OF DELEGATES — ANNUAL MEETING Meriden — May 10, 1989

Reports and Addresses

The House received reports, addresses and/or remarks from the President, Secretary, Treasurer, the Council, Delegates to the AMA, Chairman of the Board of Directors of COMPAC, the Executive Director, Connecticut Medical Management, Inc. (CMMI), M.D. Health Plan, President of the Auxiliary to CSMS, Standing Committees, Representatives and Advisors, CSMS Hospital Medical Staff Section, Delegates from Massachusetts, Vermont, and New York. (The full text of the retiring president and incoming president will appear at the end of this summary.)

Dr. Jerald R. Schenken, M.D., from Omaha, Nebraska, a Member of the Board of Trustees of the American Medical Association, was the guest speaker and presented an interesting and provocative address including his experience as nominee for the U.S. House of Representatives in the NE-2 Congressional district.

Election of Officers and Others

The House voted to approve the published report of the Nominating Committee (the Council) with minor amendments. Officers selected were:

President: Roger S. Beck, M.D., Hartford
President-Elect: Mehdi S. Eslami, M.D., Waterbury
Vice-President: Anthony P. Redmond, M.D., Greenwich

Secretary: Marjorie G. Petro, M.D., Willimantic
Treasurer: Robert R. McDonnell, M.D., New Haven
Speaker of the House of Delegates: Kenneth M. Robbins, M.D., Middletown

Vice-Speaker of the House of Delegates: Sultan Ahamed, M.D., Norwich

Councilor-at-Large: Norman A. Zlotsky, M.D., Rockville

Delegates and Alternates to the American Medical Association:

Edward A. Kamens, M.D., Fairfield (D) 1/1/90-12/31/91

Joseph C. Czarsty, M.D., Oakville (A) 1/1/90-12/31/91

Vincent J. Catrini, M.D., Middletown (D) 1/1/90-12/31/91

Annemarie S. Welch, M.D., New Britain (A) 1/1/90-12/31/91

Jerome K. Freedman, M.D., New Haven (D) 1/1/89-12/31/90

Jerome Bobruff, M.D., New London (A) 1/1/89-12/31/90

Joseph S. Sadowski, M.D., Hartford (D) 1/1/89-12/31/90

James P. Orphanos, M.D., Greenwich (A) 1/1/89-12/31/90

Stewart J. Petrie, M.D., Derby (D) 1/1/89-12/31/90

Robert M. Chmielewski, M.D., Bristol (A) 1/1/89-12/31/90

In approving the report of the Nominating Committee, the name of the present Committee on Allied Medical Services was changed to the Joint Practice Committee and a new Committee on Allied Health Services was appointed and the charges to the committee restructured.

Summary of Actions Taken

All items of business not calling for specific action by the House were accepted directly for filing. Items calling for action to be taken by the House of Delegates were heard by reference committees. Following is a list of the major actions taken:

Insurance

Voted to table until the next House of Delegates meeting a report on a Resolution on Restraints Placed on Physicians by Claims Made Professional Liability Carriers which was referred to the Council for action. Information on this subject was not available in time for the meeting of the House.

Resolution on Mandatory HIV Testing in Hospitals

Following extensive discussion it was voted not to approve the resolution introduced by the Council and other resolutions presented by the reference committee. It was voted to endorse the AMA policy on AIDS. The complete text of this policy follows:

American Medical Association

AIDS (Acquired Immunodeficiency Syndrome)

The AMA recognizes AIDS as a crucial public health problem requiring a sensitive, intelligent, effective response. Physicians should assume a leadership role in the prevention and control of this disease by educating themselves, their patients and the public.

AIDS is an infectious disease but, it is not transmitted through casual contact. Persons with AIDS and those infected with the virus should not be treated unfairly or suffer from arbitrary or irrational discrimination. (P-June 1987)

Confidentiality

The confidentiality of the doctor-patient relationship is vitally important but not absolute. There must be a judicious balance between the well being of the patient and the protection of the public health. Access to patient information should be limited to health care personnel who need access to assist the patient or to protect the health of others closely associated with the patient. (P-June 1987)

Ideally, a physician should attempt to persuade the infected party to cease endangering and to warn the third party; if persuasion fails, the public health authorities should be notified; and if the authorities take no action, the physician should notify and counsel the endangered third party. In some states, strict confidentiality laws may limit the exercise of this duty by reason of severe penalties for any breach of confidentiality, especially HIV-related information. Special legislation is needed in these states in order to grant physicians legal immunity to act in the best interests of the patient and the public health. (P-June 1988)

Physician Duty to Treat

A physician may not ethically refuse to treat a patient whose condition is within the physician's current realm of competence solely because the patient is seropositive. (P-December 1987)

Testing

Testing for the AIDS virus should be readily available to all who want to be tested. As a matter of medical judgment, physicians should encourage voluntary HIV testing for individuals whose history or clinical status warrants testing. Before testing, the patient should be counseled on effective behavior to avoid risk of AIDS for themselves and others. Patients found to be seropositive should be counseled on responsible behavior to prevent the spread of the disease, strategies for health protection with a compromised immune system, and the necessity of alerting sexual contacts within the last 5-10 years regarding their possible infection by the AIDS virus. Certain high risk groups should be regularly tested, with a right to informed consent and to refuse the test: patients at sexually transmitted disease clinics and drug clinics; first trimester pregnant women in high risk AIDS areas; and those seeking family planning from high incident areas or who engaged in high risk behavior. Testing for the AIDS virus should be mandatory for donors of blood and blood fractions, organs and other tissues intended for transplantation; for donors of semen or ova; for immigrants to the United States; for inmates in federal and state prisons; and for military personnel.

Resolution on Preserving and Enhancing the Existing Medical Care System in the United States

Voted to approve the following resolution, with a minor amendment, which was introduced by the Fairfield County Medical Association:

Resolved, That the CSMS and the AMA, not withstanding past and present lobbying activities, initiate an aggressive public education and coalition-building campaign, within the state and nationally, directed toward preserving and enhancing the existing medical system, preserving freedom of physician choice, accessibility and affordability, and proscribing rationing of services. Such a campaign will include, in public forum, rebuttal of erroneous statements, demonstration of the attributes of the existing system, exposition of weaknesses in alternate system (e.g. Canadian and European), and promotion of evolutionary improvement of the existing system to prevent the adoption of mandated socialized medicine, however it may be otherwise labeled.

Resolution on Peer Review Immunity

Voted to approve the following resolution, as amended, which was introduced by the Fairfield County Medical Association:

Resolved, That the Connecticut State Medical Society

1. Deplores recent judicial decisions permitting discovery of peer review proceedings for administrative purposes; and
2. Seek vigorously, forcefully and promptly LEGISLATIVE PROSCRIPTION against discovery of any and all such proceedings for any purpose, such proscription to be both retroactive and prospective.

Communication from Workers' Compensation Commission

A communication was introduced from the Workers' Compensation Commission concerning the implementation of Sec. 31-294 of the Connecticut General Statutes providing for an approved list of physicians furnishing medical services in workers' compensation cases. It was voted to refer this communication to the Council for consideration and action.

Awards

Dr. Norman Zlotsky, President, and Mrs. Joseph Czarsty, Chairperson of the AMA-Education and Research Foundation Awards for the Auxiliary, presented the following awards:

Yale University School of Medicine ——— \$7,280.50

Robert H. Gifford, M.D., Associate Dean for Medical Education and Student Affairs accepted the check.

University of Connecticut School of Medicine \$4,818.50

Milton Markowitz, M.D., Associate Dean for Student Affairs accepted the check.

Connecticut Science Fair Awards

Dr. Zlotsky presented the following awards:

First Place—Senior Division—Miss Alice Haven, New Milford High School

Project: "A Low Cholesterol Egg - Phase II"

First Place—Junior Division—(Joint Winners) Miss Dorothy Jalbrzykowski and Miss Diane Panus, Sacred Heart School, New Britain

Project: "Healthy Hearts Don't Grow on Trees"

Each student received a suitably inscribed plaque and a check.

Address of the President

Annual Meeting — House of Delegates

May 10, 1989

NORMAN A. ZLOTSKY, M.D.

Mr. Speaker, members of the House of Delegates, and guests: My presidential year started with two main concerns: the present and future legislative activity and the viability of MD Health Plan.

MD Health Plan as you recall was in the delicate position facing continued slow growth while attempting to maintain required reserves with a rapidly diminishing capital fund. With excellent administrative and medical board leadership making some innovative decisions, your HMO is now on solid footing. The IPA has grown to over 2000 members, and the total membership to over 21,000. Membership is 19% above expected numbers and growing. This will be one less worry for your next President.

You may also recall our debating Medicare assignment and the fateful 11:59 PM vote on the very day of the last annual meeting. I believe our strenuous efforts were not in vain: several bills to make assignment mandatory for all were killed in committee in this legislative session. Legislators are beginning to understand that cost shifting to younger patients could occur with such a bill. The most significant change in Medicare assignment in this session is the bill on the floor to require all Part B providers to give mandatory assignment at the same income levels required by physicians. In my view, that finally makes the entire mandatory assignment legislation constitutional.

Other legislative activities in this session have kept me busy. I testified on an anabolic steroid bill which would have fined a physician \$5000 for writing a prescription for an athlete. The bill has now been changed to make anabolic steroids a controlled substance, and therefore, addresses the 90%+ of the illicit drugs from non-physician sources as well. I also testified on direct patient access to physical therapists, nurse prescriptive authority, and Podiatry scope of practice. Each required a different approach. Physical therapy was asking for a significant increase in scope with no changes in training and experience. This was pointed out to the Public Health Committee in detail and the bill died in committee. An ancillary bill to disallow referral by physicians to a physical therapy office where they have a financial interest was also killed in judiciary committee after testimony explaining it was not who owned a therapy office but how well it was run professionally and ethically that decided cost control and quality of care as well as a piecemeal approach to a problem being dealt with comprehensively at the Federal level.

Nurse prescriptive authority has been difficult because

of the background involving state needs to legalize what was already being done in various state clinics. Our goal has been to keep this authority as narrow as possible and *always* under the direction of a physician. We continue to negotiate with the Health Department and nurse groups to keep our goal. Complete opposition at this point would significantly affect our credibility on all matters pending in the legislature, as well as losing the ability to further negotiate on this bill.

Increasing the scope of Podiatry was changed to a bill just reaffirming their ability to diagnose and treat foot ailments. This was accomplished by opening a dialogue which I hope will be continued by an allied health committee if you approve today. Such talks could lead to regulations specifically giving Podiatrists with appropriate further training and experience privileges not granted in the general scope of practice to all. I could foresee this accomplished through the hospital privilege process. Similarly, opening a dialogue with other limited licensed practitioners through the new Allied Health Committee may remove some of the intensively adversarial activity we have lived through. I am not wearing rose-colored glasses. At worst it would improve communications and help us better devise strategies to meet our goals. At best it would remove some adversarial legislative activity and allow the legislative committee to concentrate on a smaller number of vexing issues.

Let me also make it clear that I was not the only one who testified at the Committee hearings. Our legislative forum and president's dinner which included sections as well as counties during the fall of 1988 was successful in turning up some eloquent spokespersons who helped us with killing the triplicate prescription bill in committee as well as helping the other issues already discussed. I consider that increased physician presence at the legislature an important accomplishment. I believe the Legislative Fitness Day on March 15th sponsored by the Governor's Fitness Committee and supported by physicians of the CSMS Sports Medicine Committee and COMPAC also helped us with lobbying access to legislators while it helped over 300 legislators and capitol workers obtain some important basic health information on cholesterol, % fat, and blood pressure. I hope it will be repeated.

Other pending legislation which has reached the floor is a reversal of the State Supreme Court's ruling on disallowing naming specific amounts of non-economic damages by plaintiffs attorneys and charging of interest by physicians. Both bills came from the Judicial committee and we hope our lobbyists can convince the rest of the

legislature these are bad bills. I don't envy our lobbyists their difficult job of monitoring the sessions for the next four weeks. Any of the bills we have worked so hard on to go our way thus far could suddenly be brought up as an amendment on the floor of the House or Senate. Barring such unforeseen catastrophe, I believe this legislative session has gone well for us.

Several other issues have surfaced during the year which I will touch on briefly. CMMI which initially was set up to own the employees and property of CMIC voted to return them to CMIC because of the Connecticut law which would have required sales taxes of significant sums on such arrangements. CMMI continues in an advisory capacity to CMIC with CSMS input. An upshot of this activity discovered by Dr. Orphanos, you past president, was that the Pension Administrative Agency, a committee of the Council, with fiduciary responsibility for the CSMS employees pension plan had not met since 1981, not recognizing its charge. This has been remedied with two meetings. The first meeting utilized a checklist developed by the Pension section of Wiggin & Dana, our counsel, which in their view would carry out our fiduciary responsibility. Utilizing this checklist we determined that despite the lack of meetings of the PAA, the pension plan was fully funded, was receiving an acceptable rate of return, had filed all reports in timely fashion, and had IRS approval. Our second meeting went through the required changes to conform with the 1986 Tax Reform Act with our actuary and accountant. These recommendations were subsequently approved by the Council and referred to Wiggin and Dana for implementation. We have till 3-31-90 to make these changes and one of these changes will be a more detailed report on the pension in next years House of Delegates Handbook. The PAA will certainly continue to meet regularly.

Several recent issues are also worth noting. You all have received a letter regarding the effect on peer review of the Commissioner of Health Services vs. Harold Kadish where the Appellate Court upheld the Health Commissioner's right to subpoena administrative review records of a dental society. Counsel has advised us to look

in three directions: the supreme court which is not possible since the court has refused to hear the case, negotiation with the health department, and corrective legislation. We will keep you informed of the progress.

A two year demonstration project on biomedical waste regulation will involve Connecticut through the EPA. Specific regulations are being developed and will include physician offices. We already have a company available through the CSMS Group Purchasing Program to provide the required services. As regulations are adopted, we will keep you informed. At present, the added cost to health care does not appear great but we will continue to monitor this as well. We are also in the process of setting up a charitable trust which will be responsive to state needs as monies become available. Board members will be approved today.

In closing, I want to thank all of you who made this year a learning and growing experience for me. I must especially thank the CSMS staff: Tim Norbeck who was always there to help make the tough decisions, Josephine Lindquist who knows everything about everything, Cam Staples who helped so much on the legislative issues, Ray Sullivan who turned out a great directory and made the Legislative Fitness Day so successful, Bob Brunell whose editing kept me out of trouble with Dr. Massey, and Marc whose expertise on the budget and pension made bureaucratic mud clear as crystal. I thank you all. My inaugural speech stressed unity. The activities of the year have proven to me communication and united action are the most important parts of organized medicine's attempt to remain professional and ethical in present day society. I trust you will give Roger Beck that kind of support. In last years closing Presidential speech, Jim Orphanos mentioned the possibility of a two year presidency to improve continuity. I would respectfully disagree—a full effort for one year is almost a burn out and the presidency benefits from new blood. The key is having some experience at the start and greater involvement of the President-Elect and other officers in daily activities gives them this experience. The CSMS is in good hands.

Inaugural Address of the Incoming President

Annual Meeting — House of Delegates

May 10, 1989

ROGER S. BECK, M.D.

Thank you for this great honor. One can accept and sit back to enjoy it or one can be most appreciative of the honor and respond immediately by addressing the job to be done. I intend to do the latter because, indeed, there is a job to be done - not just by the President, nor by the Council, but by everyone of us.

It has often been said that you can be sure of only two things in life - death and taxes. I would submit there is another certainty of which you can be just as sure, and that is change. Change has come, is coming, and will continue to come at us as individual practitioners and as a professional organization, with increasing speed. Only by looking back in time can we appreciate the extent of the change which has occurred and become aware of the accelerated pace with which it is now taking place. Historians will record the passage of the Medicare Act in 1965. At that time the long-term consequences of this legislation were little noted by physicians and commented upon by only a few outsiders. However, in retrospect, it is rather obvious that the wheels were set in motion then for many of the changes we now recognize. Initially, Medicare payment for physicians' services was made directly to the patient and the patient then settled accounts with the doctor. When Medicare began to pay the doctor directly we noticed the change. Later profiles were developed for individual physicians and their fee payments adjusted. An overwhelming amount of financial data has been accumulated; this has been used, among other things to reduce specialty fee schedules. Recently, Medicare mandated that there will be no payment for certain surgical procedures unless specific criteria are met. Managed health care plans, relatively new on the scene but increasing in number, are adopting many of the same controls.

At the beginning decisions about the quality of patient care, however, were left to physicians. That, too, has changed. Perhaps our inability or unwillingness as a profession to establish standards of care has contributed to the change. Multiple studies like the Wennberg report, the Rand corporation analyses, and the HCFA mortality data have revealed in a gross way the inconsistencies, and some would say, the inadequacies, in the way we physicians deliver health care. Peer review organizations monitor the quality of our care although they have not defined it. Perhaps a description of quality of care is like that for pornography about which one observer said "I can't define it but I know it when I see it." Certainly these changes have impacted our practices and disrupted relationships with our patients.

As change after change has been made we, as individuals, and as a profession have had precious little, if any, involvement in them. Yet these changes effect us in a major way.

Should we be involved? Is there more than one answer? Of course, we must be involved! How do we get involved? My inclination is to say flippantly, with difficulty; but difficult as it may be, we cannot be outsiders as others are determining our future. How do we get involved? We must commit ourselves, individually and as a medical society, to be part of the process and not part of the protest.

Some years back I watched a small tugboat approach the Queen Mary in New York harbor. The tugboat's assignment was to dock that huge ship. Our task in many ways is the same. We push a little this way and nudge the bow a little that way - we don't stop the ship or the changes in health care but we can sure alter their course. Since we can't stop the process of change with the momentum it now has, I believe our best hope is to influence or direct the change by being participants in the planning of it. Only we can contribute our intimate knowledge of the complexities of medical care.

We as physicians can be most effective, one on one, with our own patients in describing the benefits of our present health care system. All of us entered medicine because we care about people and have a genuine interest in serving them. Through medical school and residency training we took care of our patients and experienced the rewards of patient-physician relationships, but we had little awareness of the real world of private practice medicine. Many of us were shocked to find we were not free to practice medicine as we had been taught but were restricted by confusing rules and regulations from Medicare and the many managed care companies. This situation gets worse and worse. Try to look over and beyond these onerous and burdensome restrictions. Try to rekindle the spark of idealism from your early training. Try to share with your patients your concerns about the future of health care as it effects them. By talking with your patients frankly about the changes you have seen which may compromise your ability to care for them, you can be medicine's strongest advocate. You will be starting the slow process of educating the public to the benefits of our health care system and the very real threat of a bureaucratic National Health Care System.

The role of the Connecticut State Medical Society is no more difficult than ours as individuals but is more complex. It should be emphasized right up front that the

agenda of the Society must be your interests, your issues, and your concerns. You must be heard in this House of Delegates, in the Council through your representatives, or through your direct communication with your officers. Communication is the name of the game. There can never be too much. When you have been heard the position of the Society can be established.

The Society for its part is most effective in presenting and defending these policies locally within the State. Your lobbyists, officers, members of the legislative committee, and volunteer physicians spend countless hours protecting your interests with other health care groups and in the General Assembly. Through meetings and other means of communication with the many Specialty Societies, every effort is made to establish a unified approach to the various issues. We strive to speak with one voice for medicine, to the public and in the General Assembly and its committees.

Our AMA delegates present the resolutions you have voted to the AMA House of Delegates. Your delegates are active in discussion in the Reference Committees and

floor of the House. You and the Society in this way have input through the AMA on matters at a national level. Usually, by open discussion and debate common goals can be identified and a single message from organized medicine transmitted to Congress. This year polarized views among specialty groups about the RBRVS threaten this unity.

We face many problems as changes in the practice of medicine have been forced on us. Let us accept each problem as a challenge. Communicate with your patients, communicate with each other, communicate with your Medical Society to develop a much needed spirit of unity. Participate as individuals and participate as part of organized medicine to move this huge ship called the practice of medicine in the direction we would like to see it go.

Your Society has had great good fortune in the election of capable, dedicated hardworking presidents in the past. With your help I intend to continue that tradition. Thank you for the opportunity.

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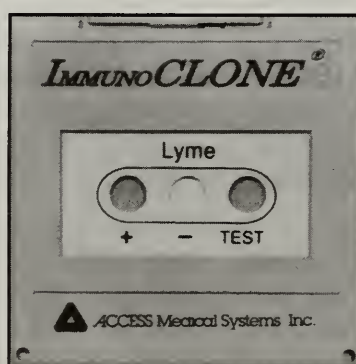
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News From the CSMS — IPA

GUY W. VAN SYCKLE, M.D.

Physician Network Still Growing

SINCE the last newsletter, 149 new physicians have joined, totaling 390 who have become participating physicians since 1 January 1989. Of these 231 are in primary care and 159 are specialists. Participating physicians now exceed 2100, the largest such list in Connecticut. Ask for our new directory.

Because of the success of our physician recruitment effort, the Board of Directors has approved the policy that no further physician waivers will be granted after 30 June 1989. Also, those physicians presently on waivers will not be approved when they are up for renewal after 30 June 1989. They may, however, along with other CSMS members, become participating physicians.

IPA Board Requires Prenotification For Outpatient Surgery

In addition to requiring precertification for inpatient admissions, the IPA Board endorsed a new policy requiring *prenotification* of all ambulatory outpatient surgery procedures. This change was in response to the striking increase in the growth and cost of outpatient surgery and the requirements of our auditors to implement required accounting procedures. Contact Diane McMunn, R.N. at M.D. Health Plan, 776-5759 or 1-800-345-9272. *Prenotification is required by the M.D. Health Plan Medical Director for the following procedures: septorhinoplasty, rhinoplasty, blepharoplasty, reduction mammoplasty and penile implants.* The Board also endorsed a sanction policy to be implemented in cases of those who chronically fail to obtain precertification for inpatient admissions.

Finance

March marked the completion of M.D. Health Plan's first profitable quarter of operations. The HMO reported a profit of \$205,000.00 to the Department of Insurance for the first quarter of 1989. This will place the HMO's equity at approximately \$1.6 million.

In April Finance completed the return of 100% of the withhold from the IPA's first contract year and anticipates a similar return in 1989. A total of \$206,000 was returned to participating physicians.

Marketing Growth Continues to Exceed Projections

Dynamic growth continued into May and early June. Our enrollment as of June 1, 1989 was 16,800 members. We continue to run approximately 20% ahead of membership projections. The combined enrollment of M.D. Health Plan and MedChoice has surpassed 20,000 members.

GUY W. VAN SYCKLE, M.D., F.A.C.P., is Medical Director of CSMS-IPA and M.D. Health Plan.

Management of Substance Abuse and Inhospital Mental Health Patients

The Board of Directors of both the CSMS-IPA and M.D. Health Plan have been acutely aware of the difficulty HMOs in Connecticut have had in their attempt to manage utilization and quality assurance in the treatment of chronic substance abuse and mental health disorders. M.D. Health Plan's own experience indicates substance-abuse services and inpatient mental health services offered in free-standing mental health hospitals to be two service categories consistently exceeding budget expectation.

With this background, M.D. Health Plan has contracted with Healthcare Management Associates (HMA) of Worcester, Massachusetts, to assist in the managed care of these services. HMA has demonstrated prior experience and outstanding capability in resources to effectively achieve the quality assurance, utilization review and budget objectives established for these services by M.D. Health Plan.

Outpatient mental health services and admissions to acute care general hospitals will *not* be affected by this arrangement. Those Plan psychiatrists directly treating substance abuse patients or directly treating chronic mental health patients in free standing mental health hospitals, will follow MDHP/HMA preadmission and concurrent review criteria, but will be paid using the existing physician fee schedule. All criteria and standards employed by HMA will be approved by the QAURRM Committee (Quality Assurance Committee of the CSMS-IPA and M.D. Health Plan). Monthly reports will be given to the QAURRM Committee to allow monitoring of the quality of care, utilization, and costs of services provided through the program.

In summary we have structured the relationship with HMA in such a way as to maximize the benefit of their experience while minimizing any disruption to participating psychiatrists when treating their patients.

Editorial Comment

The debate and discussion of the quality, effectiveness and appropriateness of health care in the United States is increasing, both in the media and in our professional literature. As a consequence of this concern, many others, in addition to physicians and patients, are becoming involved in medical decision making. Managed care plans such as M.D. Health Plan can take the lead in dealing with these concerns by developing peer driven medical practice guidelines, and by supporting the efforts of organized medicine in these areas. (ie, AMA and American College of Physicians). We must continue to dedicate ourselves to the pursuit of quality care, yet insisting that the care be efficiently provided.

Manuscripts

Manuscripts should be submitted to Robert U. Massey, M.D., Editor, CONNECTICUT MEDICINE, 160 St. Ronan St., New Haven, CT. 06511, in original and one duplicate copy. The author should retain another copy for his records. A covering letter should identify the person (with the address and telephone number) responsible for negotiations concerning the manuscript; the letter should make it clear that the final manuscript has been seen and approved by all authors.

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Manuscript Preparation

Copy must be typewritten double-spaced on (8½ x 11-inch) heavyduty, white, bond paper. This requirement applies to all text elements: references, legends, footnotes, and others. Allow generous margins on each page—at least 1½ inches at top, bottom, and left, and 1 inch at right. Pages should be numbered consecutively.

Titles and Authors' Names

The first page of the manuscript should include (A) title of paper; (titles should be short, specific, clear, and amenable to indexing. A subtitle is frequently useful in keeping the main title short); (B) name of author(s), including first name(s) and with academic degree(s); (C) List hospital positions for each author and any institutional or other credits. If an author's present affiliation is different from the affiliation under which the work was done, both should be given.

Addenda and appendices are usually not acceptable. If additional data become available before manuscript submission or final author approval, this material should be incorporated into the text.

Abstracts

The second page should contain an abstract of not more than 150 words. This abstract should be factual, not descriptive, and should present the reason for the study, the main findings (give specific data if possible), and the principal conclusions. Do not include a summary.

References

The following minimum data should be typed double-spaced: names of all authors, complete title of the article cited, name of journal abbreviated according to *Index Medicus*, year of publication, volume number, and first and last page numbers.

All references must be cited in the text. They should be arranged according to the order of citation, and not alphabetically. All references must be numbered consecutively. Numbered references to personal communications, unpublished data and "in preparation" are unacceptable. If absolutely essential, such material may be incorporated in the appropriate place in the text or as a footnote. Sample references are as follows:

1. Jones J: Necrotizing *Candida* esophagitis. *JAMA* 1980; 244:2190-2191.
2. Kremer H. Kellner E. Schierl W, et al: Ultrasonic diagnosis in infiltrative gastrointestinal diseases. *Dtsch Med Wochenschr* 1978;103 (June 9): 965-966. Abstracted, *JAMA* 1978;240:2784.
3. Influenza vaccine—recommendations of the Public Health Service Advisory Committee on Immunization Practices. *MMWR* 1979;28:231-238.
4. Fischer DH: *Growing Old in America*. New York, Oxford University Press, 1977, pp 210-216.

Tables

Data presented in tables should be self-explanatory and should supplement, not duplicate, the text or figures. Excessive tabular data are discouraged. Each table should be typed double spaced, including all headings, on separate sheets of 8½ x 11-inch paper. Oversize paper should not be used. Instead, repeat heads and stubs on a second sheet for tables requiring extra width. Number tables consecutively with respect to citation in the text. Each table must have a title.

Illustrations

Figures should be professionally drawn and photographed, if possible. Glossy, clear black and white photographs should be submitted.

Line drawings, graphs and charts should be done in India ink on high-grade white drawing paper. Lines should be examined for evenness, breaks, and proper alignment. Lettering and symbols should be clear and of even density throughout. Symbols, lettering, and numbering should be of such proportioned size that when the figure is reduced to *Journal* column width (8 cm) each item will still be distinctly recognizable.

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Each figure should have a label pasted on its back indicating the figure's number, the names of the authors, and the top of the figure. Do not mount the figure on cardboard. Do not write on the backs of figures, nor expose them to paper clips.

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Review and Action

All manuscripts are subject to review by referees in appropriate fields of medicine. Authors are usually notified within three to six weeks as to the acceptability of a manuscript, but sometimes longer delays are unavoidable.

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

AMBULATORY CARE

Full or part time position available in established south end (of Hartford) Walk-In Medical Care Center. Competitive salary; excellent hours (no weekends); incentive bonuses and buy-in options. Please send CV to David R. Howlett, M.D., Two Plymouth St., Hartford, CT 06114 or phone (203) 247-9454.

Full time or part time position available in June 1989 for physician (preferable background in Family Practice or Internal Medicine) in established Walk-In Center in Branford, CT. Pleasant working conditions; competitive salary; shoreline location. Please send C.V. to: Harry Ardolino, M.D., Coastline Medical Center, 9 Business Park Dr., Branford, CT 06405 or phone (203) 481-0818.

Full or part time position available in Newington Medical Care Center. Excellent salary, benefit, profit sharing and part ownership options available. Please send C.V. to Alex Choi, M.D., Newington Medical Care Center, 955 Main St., Newington, CT 06111.

DERMATOLOGY

Opportunity for dermatologists who seeks satellite office time in area which serves Hartford/Middletown patients. Present dermatologist in this very busy office is relocating. Please respond to: CSMS, c/o DERM/YS.

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Full time position available in new Immediate Care Facility. Physician will be offered an opportunity for profit sharing in return for day to day management duties. Salary and benefits to be negotiated. Facility is situated in northeast Connecticut. Physician will work with a group of internists. Write, CSMS, c/o EM/QB.

FAMILY PRACTICE

Board Certified/Board Eligible Family Physician wanted for rapidly expanding two man group in central Connecticut. Position available July 1, 1989. Please respond to: Jonathan Rosen, M.D., 1158 Farmington Ave., Bristol, CT 06010. 589-8882.

FAMILY/GENERAL PRACTICE

Family/General Practice in Ambulatory Care Centers providing acute and continuing care at two locations in Connecticut. Well-rounded medical background and excellent patient relation skills required. Full time position currently available. Competitive compensation, enjoyable work settings, and pleasant ancillary staff. Send CV to David E. Wilcox, M.D., FACEP, Medical Director at PhysicianCare, 28 Main St., East Hartford, CT 06118 (203) 569-8644 or PhysicianCare, 60 Church St., Yalesville, CT 06492 (203) 284-9099 or call for further information.

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Internist to join well-established 11 physician Internal Medicine Group in Central Connecticut, to practice general Internal Medicine. Substantial hospital and office patient population. Liberal salary and benefits. Send CV to: Harold P. Kaplan, M.D., Internal Medicine Associates, P.C., 116 Cook Ave., Meriden, CT 06450.

INTERNAL MEDICINE

Locum Tenens wanted for active internal medicine practice in beautiful Northwestern Connecticut. Three months assignment beginning fall of 1989. Salary plus assistance in living accommodations. Write: P.O. Box 1168, Sharon, CT 06069.

INTERNAL MEDICINE/FAMILY PRACTICE

Internist or Family Practitioner. B/C or B/E. Position available in 500-bed public psychiatric hospital and psychosocial rehabilitation facility and primarily involves out-patient level of medical treatment for psychiatric patients, as well as medical coverage of employees health clinic. Candidates must possess or be eligible for Connecticut license. Salary \$56,000-\$73,000 for 35 hours work week with no night call requirement. Benefits include comprehensive medical dental plan, generous holiday, vacation, sick and paid personal leave time, retirement plan and possible staff housing. For further information contact Lawrence Carver, M.D., Assistant Superintendent, Clinical, Norwich Hospital, P.O. Box 508, Norwich, CT 06360 (203) 823-5264. EOE/AA.

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Medical Doctor. Connecticut license required. Full or part time. Please contact Greenwich Acupuncture Center, 629-3800.

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PSYCHIATRY

JCAHO accredited 103 bed hospital specializing in the treatment of alcoholism and drug abuse seeking part-time and full-time psychiatrists to provide assessment and treatment of substance abusers with other psychiatric disorders. Must be board eligible or board certified and licensed to practice medicine in Connecticut. No routine "on call" duty. Salary commensurate with experience plus State benefit package. Please contact Dr. Elnora Maxwell, Medical Director, at 566-3039 or Dr. Marilyn Stuart, Chief of Professional Services at 566-3058, 51 Coventry St., Hartford, CT 06112.

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Aug. '89. Age 31. AB elig. MD, Sackler School of Medicine, Tel Aviv, Israel; Int., Maimonides Medical Center, Brooklyn, NY; Res., Downstate Medical Center, Brooklyn, NY. Prefers a large-sized community. Write, Ricky Zegelstein, M.D., 4600 Ninth Ave., Brooklyn, NY 11220.

GENERAL SURGERY

Aug. '89. Age 34. Nat'l bds. AB elig. MD, College of Physicians & Surgeons, Columbia University, New York, NY; Int. and Res., The Mount Sinai Medical Center, New York, NY. Prefers group or associate type practice in a medium to large-sized community. Write CSMS, c/o RA/SUR.

INTERNAL MEDICINE

July '89. Age 28. Licensed in Connecticut. Nat'l bds. AB elig. MD, Brown Medical College, Providence, RI; Int. and Res., St. Francis Hospital, Hartford, CT. Prefers southwestern Connecticut. Write, Emilio Melchionna, M.D., Apt. C-1, 20 Gillett St., Hartford, CT 06105.

Feb. '90. Age 28. Licensed in Connecticut. MD, The Hebrew University — Hadassah, Jerusalem; Int., Sackler School of Medicine, Telhashomer, Israel; Res., Kaplan Hospital, Hadassah Medical School, Israel (IM); Fellowship, Bellinson Medical Center, Sackler School, Israel and Albert Einstein College of Medicine, NY (CARD). Open to any type practice and location. Write, SA/IM.

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Aspartame: Clinical Update

DANIEL P. POTENZA, M.D. AND RIF S. EL-MALLAKH, M.D.

ABSTRACT—Since the introduction of aspartame into the American food supply in 1981, it has grown to become the most widely used and accepted artificial sweetener. However, recent published and unpublished reports of headaches, seizures, blindness, and cognitive and behavioral changes with long-term, high-dose aspartame may be cause for concern. Physician awareness of the present clinical and research status of aspartame is important.

ASPARTAME (Nutrasweet®, Equal®, Fliks®) is a dipeptide methyl ester composed of aspartate, phenylalanine, and methanol (Figure 1). It is presently widely used as an artificial sweetener. Nearly 200 times sweeter than sucrose, aspartame provides the same sweetness with only 5% of the caloric content.¹ It has become so popular with the weight-conscious American populace that it is now available in over 1,500 food products.²

The wide acceptance of aspartame belies its tumultuous history. James Schlatter of G. D. Searle Laboratories discovered aspartame in 1965. In 1971 Searle felt it had sufficient evidence for aspartame's safety to approach the United States Food and Drug Administration (FDA) for approval. Concerns regarding potential tumorigenicity^{3,4} for brain lesions, and endocrine dysfunction,⁵⁻⁶ delayed approval until 1981. At that time a Public Board of Inquiry that had examined the available experimental data concluded aspartame is safe for human consumption.^{7,8}

In more recent years, several published and unpublished anecdotal reports of headaches, seizures, blindness, cognitive and behavioral changes, and a host of less severe symptoms have been associated with aspartame use. Although the validity of some of these associations is suspect, the often similar presentations and the potential severity of these reactions requires that a detailed investigation be undertaken. This paper critically reviews the basic physiological data and applies them to a clinical update of aspartame.

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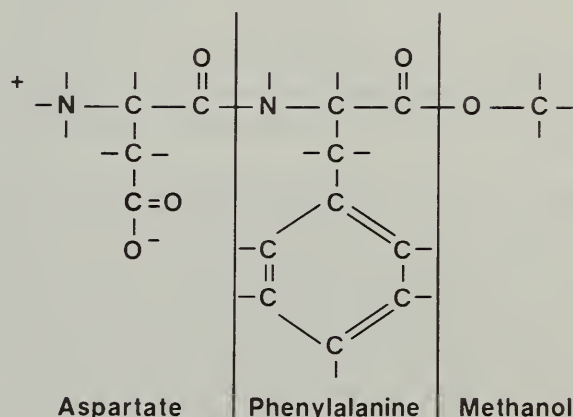


Figure 1
Aspartame (L-aspartyl-L-phenylalanine methyl ester).

Aspartame: Background

Aspartame is composed of phenylalanine (50% by weight), aspartate (40% by weight), and methanol (Figure 1). It is quite stable in its crystalline form, but breaks down relatively rapidly in a liquid environment. Degradation may be further accelerated by increases in temperature or acidity. Consequently, if a carbonated beverage is stored at 30C for eight weeks, some 38% of the aspartame would breakdown (Figure 2). Of the breakdown products some 12% is diketopiperazine, 10% methanol, and the balance is the benign dipeptide or component amino acids.⁹ These products are not more toxic than consumption of the entire aspartame molecule. In practical terms, however, this means that diet soft-drinks must be "oversweetened" to insure adequate shelf life. This may have significant implications regarding projections of aspartame intake. Some of these factors were instrumental in the two-year delay of the approval for the use of aspartame in beverages.¹⁰ Residents of hotter climates remain concerned. In 1984, the Arizona Dietetic Association and the Central Arizona District Dietetic Association filed a petition with the Arizona Department of Health Services to ban the sale of aspartame-sweetened beverages in Arizona.¹¹ (The mean high daily temperature in Phoenix is 85.1F). The Department of Health rejected the appeal, citing the voluminous FDA data of safety.

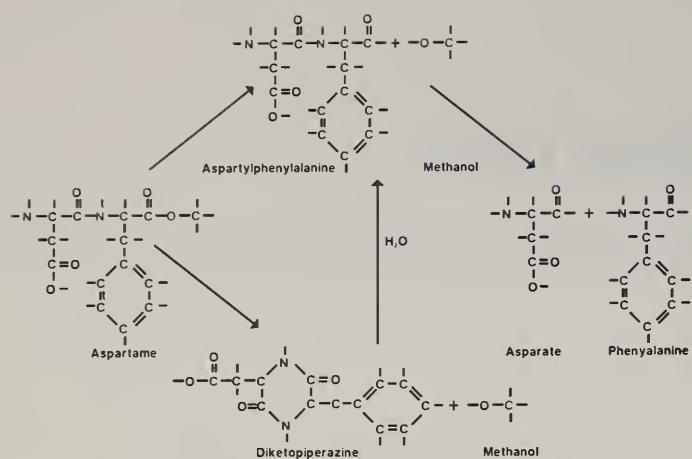


Figure 2

Degradation of aspartame in solutions or in the gut or liver. Methanol is released to form either aspartylphenylalanine or diketopiperazine; these, in turn, breakdown to the component amino acids: aspartate and phenylalanine.

Distressingly, most studies and conclusions of aspartame safety are based on the projection that 34mg of aspartame/kg of body weight/day is the 99th percentile intake.^{12,13} This figure was composed in the early 1970s, before aspartame's introduction to the market-place. Since its introduction, however, aspartame has found its way into over 1,500 food items,² and consumer acceptance has rocketed it from a \$13 million/year business in 1981, to over a billion dollars in 1986.¹¹ The ubiquitous distribution of aspartame means that consumption may easily exceed 34mg/kg/day in many individuals. Nonetheless, even recent studies continue to use this figure as the projected maximal intake.

Aspartame Metabolism

Aspartame is absorbed and metabolized as a dietary dipeptide. It may undergo hydrolysis by intestinal brush border peptidases, or may be absorbed whole and hydrolyzed by intracellular peptidases in the gut or in the liver (Figure 2).¹⁴ The metabolism of the three components of aspartame occurs principally in the liver, but other organs, particularly the brain, may play a significant role. We will review the metabolism of each component.

Phenylalanine. Phenylalanine is a large neutral variably essential amino acid. The first step of phenylalanine metabolism is hydroxylation to tyrosine.¹⁵ The two amino acids serve as substrates for such diverse compounds as the neurotransmitters dopamine, norepinephrine, and epinephrine; the pigment melanin; coenzyme Q of the electron transport system; and the skeleton of triiodothyronine (T₃) and thyroxine (T₄).¹⁵ The average daily American consumption of 100 gms protein/day provides nine to 10 times the estimated adult requirement—about 4.6 gms/day of phenylalanine and 3.6 gms/day of tyrosine.¹⁵ Human infants require significantly greater amounts. Of the total infant aromatic amino acid requirement of 141 mg/kg/day, phenylalanine provides 65 mg/kg/day and tyrosine provides 76

mg/kg/day.¹⁵ But the relative requirements are not fixed, for example, in the growing rat the phenylalanine requirement can grow from 0.7% of the diet when tyrosine is present, to 0.9% of diet when it is absent.¹⁶

Phenylketonuria (PKU) is the best studied condition of deranged phenylalanine metabolism. Transmitted as an autosomal recessive trait, it is characterized by the total absence of phenylalanine hydroxylase.¹⁷ In the United States, one of every 60 individuals is heterozygous for a defective phenylalanine hydroxylase; and the homozygous incidence of the disease is 1/15,000 births.^{15,17} However, with multiple alleles and at least three isoenzymes of phenylalanine hydroxylase,¹⁸ the incidence of non-PKU hyperphenylalaninemia is 20/15,000 births.¹⁷ Routine fasting phenylalanine level may be normal, but the ability to clear a phenylalanine load is often mildly impaired in PKU heterozygotes,^{19,20} and greatly impaired in hyperphenylalaninemia.²¹ Interestingly, protein-energy malnutrition (which may be approximated by dieting to lose weight), may mimic or exacerbate phenylalanine hydroxylase deficiency.²²

Chronic hyperphenylalaninemia may have deleterious effects in genetically intact individuals. For example, when dietary content of phenylalanine exceeds the capacity of the phenylalanine hydroxylase system (ie, approximately 5% of total diet) growth retardation results.²³ In both infants and adults phenylalanine may compete with other large neutral amino acids for entry into the brain resulting in changes in the relative distribution of amino acids²⁴ and neurotransmitters.²⁵ Increased tyrosine production resulting from hyperphenylalaninemia, causes increased catecholamine synthesis in conditions in which catecholaminergic neurotransmission is stimulated, eg, spontaneously hypertensive rats.^{26,27}

These findings would have obvious implications on aspartame consumption since the metabolic responses to the phenylalanine component of aspartame are identical to equimolar amounts of phenylalanine.²⁸ Thus, rats given aspartame 200mg/kg exhibited significant changes in brain levels of phenylalanine, tryptophan, and tyrosine (all are neurotransmitter precursors), and nonsignificant trends in the levels of brain catecholamines and monoamines.²⁸ The clinical implications of these reported changes remain unclear, however, there may be an association with reports of aspartame-related mania²⁹ and seizures.³⁰

Aspartate. Aspartate is a nonessential amino acid. It shares many properties with the structurally similar amino acid glutamate. Both are found in large amounts in the human diet, including human milk;³¹ and both are rapidly absorbed and rapidly metabolized, mainly via the citric acid cycle.³¹ Of particular interest, is that their potentially toxic effects are additive.

Approximately 20% of a rodent population will exhibit histopathological signs of hypothalamic necrosis when given aspartate³²⁻³⁵ or glutamate^{32,36,37} or a combination at a dosage of 500mg/kg. Although the pathophysio-

logic mechanisms are unknown, they may stem from the action of glutamate and aspartate as excitatory neurotransmitters.^{38,39} It was partly the demonstration of this neurotoxic potential that helped to discredit liquid protein diets (which may contain as much as 25% aspartate + glutamate) in the 1970s.⁴⁰

Aspartame also produces neuronal necrosis in infant mice, much the same way as aspartate.⁴¹ However, the same doses (aspartame 2gm/kg, containing aspartate 800mg/kg), do not produce any brain lesions in infant macaques.⁴¹⁻⁴³ In the macaque studies, mean plasma aspartate levels peaked at 49umol/dl, much lower than the 60-200umol/dl seen following similar doses in rodents.⁴⁴ This interspecies difference remains unexplained, and despite arguments to the contrary,⁴³ actually raises more doubts about the applicability of any animal studies to the human situation.

Methanol and Diketopiperazine. Methanol is the third component of the aspartame molecule (Figure 1). Diketopiperazine is a breakdown product of aspartame (Figure 2). They are discussed here together because they probably are the least problematic components. Methanol, a known toxin, is widespread from man-made sources (antifreeze, fuels, photocopy machines) and natural sources (fresh fruit and vegetables).⁴⁵ Even at high aspartame doses the liver can rapidly detoxify methanol to carbon dioxide and water via the alcohol dehydrogenase or catalase systems.⁴⁵ However in folate deficiency, there is decreased breakdown of the toxic intermediate formate (since folate serves as a cofactor for formyltetrahydrofolate dehydrogenase), which may result in the signs of methanol toxicity.⁴⁵

Diketopiperazine (Figure 2) is a known toxin which received significant attention in the early 1970s. It appears that the liver is very efficient at detoxifying this compound even at very high doses.⁹

New Clinical and Theoretical Concerns

Since 1985 there have been increasing numbers of reported clinical syndromes associated with aspartame intake. Additionally, human and animal research, which has shifted to study the more subtle effects of aspartame ingestion, is producing rudimentary but distressing results. The more important of these clinical syndromes will be discussed.

Importance to Clinical Medicine and Psychiatry

Several case reports associate aspartame consumption with a variety of medical^{29,30,46-48} and psychiatric conditions.^{29,48-49} Furthermore, passive surveillance carried out by the FDA revealed many varied consumer complaints involving aspartame.

Following the introduction of aspartame in carbonated beverages in 1983,¹⁰ the FDA approached the Centers for Disease Control (CDC) to analyze a variety of consumer complaints. Reported initially in 1984⁵⁰ and then more fully in 1986,⁴⁸ the CDC study revealed a variety of common, reproducible symptoms among the

preselected population of 231 complainants (Table 1).

Table 1
Reports of common complaints linked by consumers to their aspartame consumption in 231 complainants (note: there may be multiple complaints per individual).

Symptoms	%
NERVOUS SYSTEM (n = 91)	
Headache	45
Anxiety, Irritability, Depression	43
Insomnia	22
Dizziness	21
Fatigue	20
Visual Impairment	9
Numbness	7
GASTROINTESTINAL (n = 35)	
Abdominal Pain	46
Nausea	43
Diarrhea	31
Vomiting	23
SKIN (n = 23)	
Rash (or other "allergic" symptoms)	
MENSTRUAL IRREGULARITY (n = 8)	

The majority of these individuals were white (94%), women (75%) with a normal-curve age distribution. Most (63%) had more than one symptom. Fifty-five individuals were able to clearly reproduce their symptoms when rechallenged with aspartame-containing products. There has not been a follow-up study of side effects in the general population.

However, a recent study which solicited subjects who suspected that aspartame may influence their headaches, showed that 300 mg/day of aspartame (administered in a double-blind cross-over fashion) increased common migraine frequency in 11 subjects from a mean of 1.71 headaches/month to 3.55 headaches/month ($p<0.02$).⁵¹

Among the pediatric population, initial reports of aspartame's altering behavior in attention deficit disorder and hyperactivity⁵² have not been confirmed in more recent studies.⁵³⁻⁵⁵

Perhaps the most striking presumed medical complications of aspartame ingestion are blindness⁴⁶ and seizures.^{29,30,56} Reports of partial or complete visual loss secondary to aspartame in as many as 60 patients have been well publicized⁴⁶ but never published, raising a serious question to the validity of these reports. Presumably, the loss of vision is related to the methanol component of aspartame. However, the appearance of methanol-damaged discs⁵⁷ is difficult to distinguish from a wide variety of ischemic optic neuropathies.⁵⁸

Richard Wurtman, M.D., of the Massachusetts Institute of Technology, has gathered 80 patients in whom seizures have been linked to long-term, high-dose aspartame consumption (personal communication, 1987). Aside from the original published case reports,^{29,30} a detailed description of these seizure-susceptible individuals has yet to be published. However, there appears to

be significant similarities in the unpublished cases.⁵⁹ Often they were young to middle-aged women who consumed large quantities of aspartame for several months. The seizure event was frequently preceded by a prodrome of weeks or months of severe headaches.⁵⁹ This has implications regarding future study design and suggests that acute dosing studies, or even studies designed to administer aspartame over a period of a few weeks, would not lower seizure threshold.

Cognitive Changes Related to Aspartame Intake

Early acute dosing studies conducted by Waisman and Harlow⁶⁰ investigating the effects of phenylalanine on learning in infant monkeys demonstrated deficits on some of the more difficult tasks on the Wisconsin General Testing Apparatus Protocol.

More recently Krause et al⁶¹ examined the effects of elevated plasma phenylalanine on neuropsychological test performance of adult humans with treated PKU. Specifically, they attempted to distinguish effects of elevated phenylalanine plasma levels on higher integrative function (a measure of decision-making abilities) and lower integrative function. While the tests measuring the more fundamental integrative functions were not affected, those measuring higher integrative skills and decision making were. In fact, a 77% increase in plasma phenylalanine (resulting in a 63% decrease in urinary dopamine) was paired with an 18% decrease in higher integrative performance.⁶¹

Similar findings were noted in an unpublished preliminary trial of normal young adults receiving high-dose aspartame (50mg/kg body weight) over a 12 day period.⁶² These normal adults and placebo-treated controls were tested with a variety of neuropsychological tests. These included the Trailmaking, Stroop Interference, and "Think Fast," all of which test attention and the ability to vary the response strategy, ie, they approximate "the complexity at which the brain has to function in every day life."⁶² In the small preliminary sample of four experimental subjects there was a trend toward statistical significance with aspartame reducing performance in these complicated tasks.⁶²

Conclusions regarding what effects aspartame may indeed have, especially considering the chronic, high intake patterns many individuals demonstrate, remain unclear. As this discussion indicates, there exists a strong need for further focused research in this area.

Aspartame Ingestion During Pregnancy

Aspartame's amino acid composition renders it of special concern to the pregnant population. In humans, plasma levels of most free amino acids in the fetus exceed that of the mother.⁶³ This transplacental gradient, which offers many developmental advantages to the growing fetus ensuring sufficient amounts of essential building blocks is maintained. For example, the fetal plasma phenylalanine concentration is approximately one and a half to two times the maternal plasma concentration.

However, the fetus may be less able to metabolize phenylalanine. Studies of phenylalanine transport in the rat have demonstrated that at excessive levels, the fetus is much less effective than the adult in metabolizing phenylalanine. This results in significant fetal exposure to elevated plasma phenylalanine for considerable lengths of time.⁶⁴

Infants born to women with PKU, with very high maternal phenylalanine plasma levels, very often demonstrate evidence of prenatal brain damage as a result of this placental augmentation.⁶⁴

In normal pregnant humans, fasting phenylalanine levels, which are approximately 3-5 umol/dl, might be expected to double following a phenylalanine-containing meal.⁶⁴ This would result in fetal levels of approximately 12-20 umol/dl, which, by demonstration, is nontoxic. Similarly, when aspartame is given to normal adults at what was in the 1970s the projected 99th percentile of the daily aspartame consumption (34mg/kg), plasma phenylalanine levels rise to 7.0 umol/dl.⁶⁴ This situation would resemble that of a protein meal, again being essentially nontoxic. However, since its introduction, the availability of aspartame has greatly increased and as of June 1986 aspartame was available in over 1,500 products.² It is well worth the thought that the projected 99th percentile of 1988 far exceeds that of the 1970s. Inadequate knowledge exists on the effects of this consumption increase on the pregnant population. At best these issues remain controversial and further research is clearly indicated.

At-Risk Population

Why certain individuals seem to be effected by high aspartame consumption and others are not remains unclear. It has been previously stated that there is a wide range of hyperphenylalanemias with blood levels ranging from 100mg/dl to those bordering on normal level of 0.4mg/dl.¹⁸ Multiple alleles and multiple isoenzymes help to explain some of this phenotypic diversity.

It is important to note that many of these hyperphenylalanemias would not be readily identified by the Guthrie test (the routine urine screen for classic PKU). Consequently, it may be possible that the "at-risk" population is a group of individuals with some phenylalanine hydroxylase abnormality which may become clinically evident with more widespread use of aspartame in the general population.

Summary

Although reliable epidemiological data are seriously lacking, and important, pertinent data remain unpublished (and consequently protected from peer review), there appear to be sufficient data to indicate that a sector of the population may be susceptible to a variety of complications with long-term, high-dose aspartame ingestion.

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Patient Whose Picture Was Used Sues Hospital, Physician And Others

A patient had a cause of action for breach of physician-patient privilege arising from the unauthorized use of his picture in a newspaper article on AIDS, a New York trial court ruled.

The patient allegedly was HIV positive but did not actually suffer from AIDS. He was in the waiting room of a hospital infectious disease unit that was involved with AIDS research and treatment when a nurse asked him if a newspaper photographer could take his photograph. He was assured by the nurse and a physician that a silhouette picture from a back angle would be taken and that it would not be recognizable.

Two days later, the patient's photograph appeared on the front page of a section of the newspaper with a caption about the physician, whose chief responsibility was caring for AIDS patients. The patient learned of the publication when a family friend asked him if it was his picture.

The patient sued the hospital, the physician, the nurse, and others, alleging, among other things, breach of the physician-patient privilege. He claimed that publication of his picture had caused him and his family to suffer. He was afraid of venturing outside his home and was receiving professional counseling.

The medical parties contended that they did not disclose information obtained from the patient in confidence. The court said that the fact that a person had received treatment was as much confidential information protected by privilege as was the nature of the treatment.

The court said that the patient did not consent to the publication of a recognizable photograph. Nor did he consent to the presence of the photographer and a reporter in the waiting room. The court said that by their permitted presence, especially for the purpose for which they were there, the patient's immunity from disclosure as a patient was violated. Therefore, the medical parties could be held accountable to the extent that confidential information as to the patient's identity and treatment was disclosed.

The court said that an important objective of an AIDS clinic was to encourage people suffering from AIDS or who suspected that they might be infected by the virus to go for testing and treatment without fear of public disgrace or shame. Thus, the medical parties' breach was not merely a broken contractual promise but a violation of a fiduciary responsibility implicit in and essential to the physician-patient relationship.—*Anderson v. Strong Memorial Hospital*, 531 N.Y.S.2d 735 (N.Y. Sup.Ct., July 27, 1988)

— AMA-The Citation

Mycobacterium Avium Intracellulare as a Marker of Human Immunodeficiency Virus Disease

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ABSTRACT—Between January 1981 and December 1986, 4,178 patients were cultured for mycobacteria at a community teaching hospital in Hartford. The number of patients with positive cultures totaled 278 (6.65%). *Mycobacterium other than tuberculosis* (MOTT) was isolated from 228 (82%). MOTT isolation increased yearly from 1.5% of the patients in 1981 to 14.5% of the patients in 1986. *Mycobacterium avium intracellulare* (MAI) was the most common MOTT species isolated (197/228). Fifty-nine patients were under the age of 50, but 23 had predisposing factors for MOTT. Of the 36 who did not have an underlying condition, 25 had the human immunodeficiency virus (HIV). The isolation of MAI preceded the diagnosis of AIDS/ARC in nine patients, in 10 others it coincided with their diagnosis and in six it followed the diagnosis. Isolation of MAI in a patient under the age of 50 with no predisposing factors may suggest concomitant HIV disease.

Introduction

MYCOBACTERIUM avium intracellulare (MAI), an atypical mycobacterium, is not common in New England,¹ but in the past few years, with the onset of HIV disease,² we have become aware of an increasing number of MAI isolates from patients at this hospital in Hartford.

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The increase in MAI may be related to the increasing number of patients with HIV disease in Connecticut. The first case of AIDS in Connecticut was seen in 1981. By the end of 1986, 356 cases had been reported, 80% since June 1984.³

Although MAI has become an important pathogen in patients with HIV disease, the present study was undertaken to review the charts of patients from whom MAI had been isolated and to determine if it is a marker for HIV disease.

Material and Method

The records of the section of microbiology at St. Francis Hospital and Medical Center, a 700 bed community teaching hospital in Hartford, were reviewed from January 1981 through December 1986. All patients who had specimens from any source submitted for culture, the number of cultures that were positive, and the species of mycobacterium isolated were recorded for each patient.

Sterile tissue homogenates and body fluids with volumes < 10 ml were plated directly onto media. Body fluids with volumes > 10 ml were subjected to centrifugation and the sediment inoculated onto media. All respiratory and other specimens likely to be contaminated with bacteria other than mycobacteria were decontaminated by 4% NaOH-N-acetyl-L-cysteine method before configuration.⁴

All specimens were inoculated onto the following media: one 7H12 vial (BACTEC) containing C¹⁴-palmitic acid (Johnston Labs), one Mycobactosel Lowenstein-Jensen slant containing 3.2 GK36 µg lincomycin and 56 µg nalidixic acid and one Middlebrook 7H10 slant (Scott Labs). The Bactec 7H12 vials inoculated with decontaminated specimen concentrates were supplemented with 0.1 ml of the antimicrobial additive pack (polymyxin B 50 U/ml, amphotericin B 5 µg/ml, carbenicillin 25 µg/ml, trimethoprim 2.5 µg/ml). AFB isolates were sent to the Connecticut State Health Department

Laboratory for confirmation and speciation by conventional biochemical techniques.

The medical records discharge files were used to obtain information on the age, sex, and primary diagnosis of each patient.

Results

From 1 January 1981 through 31 December 1986, 4,178 patients were cultured for acid-fast bacilli (Table 1) Two hundred seventy-eight of these patients had cultures positive for mycobacterium from at least one specimen. The number of patients cultured annually showed no significant increase during this time period. However, the percentage of patients who were cultured positive increased from 2.9% in 1981 to 16.03% in 1986. This increase in positive cultures was due to an increase in the number of patients from whom *Mycobacterium other than tuberculosis* (MOTT) were isolated. Those patients with MTB did not increase significantly in the study time frame. Eighty-six percent of the MOTT cultures were MAI.

Table I

	1981	1982	1983	1984	1985	1986	Totals
PTS. Cultured	605	607	719	768	749	730	4178
MTB	9	11	9	6	4	11	50
MOTT	9	18	28	32	35	106	228
MOTT (MAI)	9	13	23	25	31	96	197
% + Cultures	2.98	4.77	5.14	4.95	5.20	16.0	6.65

Table II indicates the profile of all MAI patients while Table III shows only those patients under the age of 50.

HIV testing was not done on the study population. Through review of the medical records, 25 patients were found to have HIV disease. All were under the age of 50. As Table II indicates, 80% of these patients had multiple positive cultures for MAI.

Table II - Profile of MAI Patients

	1981	1982	1983	1984	1985	1986	Totals
0 - 50 Yrs	3	1	4	6	14	31	59
> 59 Yrs	6	12	19	19	17	65	138
Male	6	9	18	19	18	65	135
Female	3	4	5	6	13	31	62
+ Cultures:							
1	6	6	16	19	19	78	144
> 1	3	7	7	6	12	18	53
Source:							
Sputum	6	8	14	19	16	43	105
Bronch.	1	1	2	2	5	34	45
Other	2	1	4	2	5	8	22
Multiple	0	3	3	3	5	11	25

Twenty-three of the patients under the age of 50 had predisposing factors for MOTT. Of the remaining 36, 25 either had or developed HIV disease. This isolation of MAI preceded diagnosis of HIV in nine of the patients by a mean of 6.3 months (range 1-32 months). MAI and HIV were concomitant in 10 patients and followed the

HIV diagnosis in six patients by a mean of eight months (range 1-21 months).

Twenty-five of the 36 patients with no predisposing factors for MOTT (69.4%) had or developed HIV disease. None of the 138 patients over the age of 50 with MAI had or developed symptoms of HIV disease.

Table III
MAI Patients < 50 With HIV Disease

	1981	1982	1983	1984	1985	1986	Totals
Male	0/3	1/1	0/4	1/4	7/11	13/22	22/45 (48.9%)
Female	0/0	0/0	0/0	0/2	1/3	2/9	3/14 (21.4%)
Totals	0/3	1/1	0/4	1/6	8/14	15/31	25/59 (42.4%)

During the period of this study, 42 patients were diagnosed as having AIDS. Twenty-one (50%) of these patients had MAI. Two or 9.5% of these patients were diagnosed with MAI at least one year preceding the diagnosis of AIDS (Table IV).

Discussion

Atypical mycobacteria are being noted with increased frequency in the northeastern United States. In Massachusetts, du Moulin¹ reported in 1983 that MAI was approaching *Mycobacterium tuberculosis* (MTB) as the most frequent mycobacterial organism cultured. That occurred in Connecticut as early as 1982. With the recognition of AIDS in 1981 and identification of MOTT as etiologic agents in opportunistic infections, more attention has been directed to these organism.^{5,6,7}

In this study we did not attempt to identify colonization versus disease. The majority of patients had MAI isolated from pulmonary sources; however, blood, urine, stool, bone marrow, and lymph nodes also grew out the organism.

Predisposing conditions for MOTT include a history of tuberculosis, chronic bronchitis, pneumoconiosis, chronic obstructive lung disease, bronchiectasis, and esophageal disease resulting in aspiration. These infections are also associated with underlying malignancy and impaired immune system disorder such as AIDS and immunosuppressive therapy.⁸

Connecticut ranked 14th in the United States at the end of 1986 with 356 AIDS patients reported. There has been a yearly rise in cases of AIDS in this state since reporting began in 1982. Altered cellular immunity predisposes these patients to MOTT infections. However, initially the significance of these isolates in AIDS patients was downplayed and clinical problems attributed to other opportunistic infections. Sohn⁹ reported MAI isolation from two AIDS patients who had received no antimycobacterial therapy and who had subsequently died from disseminated MAI confirmed by autopsy. MAI is reported as the most common mycobacterial organism cultured from AIDS patients.¹⁰

Zakowski¹¹ reported that in AIDS patients other opportunistic pathogens such as cytomegalovirus, pneumocystis, and/or cryptosporidiosis are always present as

well when MAI is recovered. Pichenik¹⁰ cited five AIDS patients who had MOTT cultured concurrently or post-dating the recognition of *Pneumocystis carinii* pneumonia, toxoplasma encephalitis, or Kaposi's sarcoma. More frequently, MAI infections are found just prior to death or at autopsy in AIDS patients.¹² The results of this study revealed nine patients who had positive MAI cultures isolated prior to the diagnosis of AIDS, and 10 concomitant with the diagnosis. This suggests that the isolation of a MOTT organism in a patient at risk for AIDS/ARC may provide an early warning sign. All 25 patients with HIV disease in this study were under the age of 50 which is the population most frequently diagnosed with AIDS.^{13,14}

Table IV
Aids and MAI

	1981	1982	1983	1984	1985	1986	Totals
AIDS Diagnosed at SFHMC	0	0	2	1	14	25	24
These pts. with MAI	0	1	0	1	7	12	12

0 = MAI preceding diagnosis

Much other information can be obtained from this study of 4,178 patients. Routine HIV testing was not performed on all patients. Therefore, some patients may not have been identified as HIV positive, including those over the age of 50. Without long-term follow up or HIV testing, we cannot determine which patients will develop HIV. However, this paper has attempted only to consider those patients under the age of 50 who had positive cultures for MAI.

Summation

Of the 59 MAI patients under the age of 50, 23 had multiple positive cultures. Nineteen (82.6%) of these had or developed HIV disease. Of the 36 patients under the age of 50 with single positive cultures for MAI, six (16.7%) developed HIV disease. In this nonendemic area for MAI, the isolation of this organism on more than one

occasion from a patient under the age of 50 may suggest HIV disease. All patients with MAI should have HIV testing regardless of predisposing factors.

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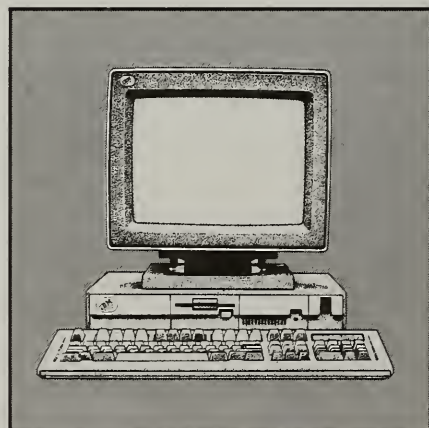
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Prealbumin: A Biochemical Marker of Nutritional Support

WALTER E. PLEBAN, M.D.

THE workup of a hospitalized patient should include nutritional assessment in order to provide optimal treatment. There has been a shift in the past several years from formal anthropometric and biochemical parameters to a subjective global assessment to determine which patients will benefit from nutritional support.¹ However, one simple test, the serum prealbumin determination, has proven to be a superior marker to identify the malnourished patient.²

In this paper we will report the approaches used in evaluating nutritional status, and point out the importance of a single biological marker, prealbumin, in this effort.

Measurement of serum albumin has been used in population studies as an indicator of visceral protein depletion. However, this marker has proven to be a poor indicator of early protein malnutrition, as serum levels fall and rise slowly with changes in nutrition. Albumin has a half-life of 20 days, which is too long for it to be useful in measuring current status and, more importantly, changes in status.^{3,4}

A decrease in serum albumin generally indicates a decrease in the synthesis of liver protein resulting from a limited supply of substrate. However, an increase in extracellular fluid, can result in a false decrease in serum albumin. It is common to see decreased albumin levels in patients following surgery, trauma, or sepsis, as the result of increased metabolism, edema formation, or increased peripheral retention of protein.⁵

Levels of albumin below 3 g/dl correlate with increased morbidity and mortality. This has been recognized for the past two decades and reported by numerous authors. Andrassy has introduced the concept of stabilizing albumin loss by albumin infusion for nutritional support; once the albumin level is stabilized, enteral nutrition is continued to keep the albumin level elevated with improved liver albumin production.³ This concept has yet

to be generally adopted but is being reviewed by researchers in the field. It offers a method of maintaining elevated serum albumin levels.

At Bridgeport Hospital the nutrition support team has examined the problem of clinical and biochemical markers of nutritional status, and has concluded that the prealbumin serum level is an accurate indicator of nutritional status. Bernstein found the prealbumin marker to be the most reliable index in nutritional assessment. His paper on the usefulness of prealbumin was presented at the American Society for Parenteral and Enteral Nutrition Clinical Congress in January 1988. He also developed the test kit for Beckman Incorporated.^{2,4}

We have used the prealbumin marker at Bridgeport Hospital for the past three years and have found it to be an excellent dynamic marker in the stressed hyperdynamic patient. Every patient admitted to the burn center and most patients admitted to the medical and surgical intensive care units have a serum prealbumin determination on admission and then twice weekly thereafter.

In a personal communication Dr. James Mullen at the University of Pennsylvania Hospital informed me that he and his staff have been using the prealbumin test as their biochemical marker, and have found it a reliable test of both the need for nutritional support and change in nutritional status.

The prealbumin test is inexpensive and results are available in 24 hours. Prealbumin has a half-life of 48 hours; variations are therefore noted from one study to the next. Once nutritional support is instituted in a hyperdynamic or nutritionally deprived patient, prealbumin levels may rise or fall rapidly, more accurately reflecting the efficacy of nutritional support.⁴

We have found that prealbumin levels in the treated population have varied from a low normal of 10.3 mg/dl to 13.5 mg/dl. The malnourished patients averaged from 6.5 mg/dl to 13 mg/dl with levels above 13 mg/dl reflecting a return to normal status. With continued nutritional repletion and general improvement in medical status, levels as high as 35 mg/dl were reached.²

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Prealbumin is the carrier protein for the retinol-binding protein and plays a major role in the transport of thyroxine. The total body pool of prealbumin is small, and sudden demands for protein synthesis, as after surgical procedures, trauma, and sepsis depress prealbumin levels. Low levels are important indicators of critical need for nutritional support. A poor prognosis for life may be seen at levels of 5 mg/dl and below.

In reviewing patients on parenteral nutrition during the past three years, we noted that prealbumin levels rose rapidly for those patients who improved clinically. At the same time, it took two to three weeks to show significant albumin level increases for these same patients.

Bernstein in 1987 compared albumin and prealbumin levels to determine nutritional support effectiveness in 40 patients managed with enteral or parenteral support. Serum prealbumin changed rapidly and reflected more accurately the nutritional status of the patients than did albumin. Using Shannon Information Measures Rudolph was able to show unequivocally that prealbumin levels correlated well with clinical and nutritional progress.²

Leider has reported her use of prealbumin testing in approximating nitrogen balance. She has shown that a prealbumin of 18 mg/dl correlates with a zero nitrogen balance; thus she is able to determine from the prealbumin level that the patient is in balance.⁶ Thomas reported with her colleagues that in the neonate, prealbumin was the most accurate and inexpensive marker of nutritional status. She studied only high risk sick infants.⁷ Fletcher et al reported that serum prealbumin and transferrin were the most useful indicators of nutritional status.⁸

Church and Hill have found prealbumin to be the most suitable plasma protein marker for use as a dynamic index of nutritional support, and superior to transferrin, to albumin, and to retinol-binding protein.⁹ These authors postulated that a rising transferrin level is a reasonably good indicator of positive nitrogen balance, but a falling transferrin level is a poor indicator of reserves. They stated that it may be possible to utilize the difference in the half-life of plasma prealbumin and plasma transferrin to construct an index of changing nutritional status from a single plasma sample. They propose that if transferrin is low and the prealbumin level high, the nutritional status is improving. This relationship is suggested since prealbumin is more labile than transferrin. If the prealbumin level is low and the transferrin high, the nutritional status may be deteriorating.

Serum transferrin is synthesized in the liver and has proven to be a good indicator of change in visceral protein, but because of its half-life of eight to 10 days, it changes too slowly to reflect rapid changes in nutritional status.⁴

Other biochemical factors, such as retinol-binding protein, creatinine-height index, urinary 3-methyl histidine excretion, 24-hour urinary nitrogen excretion, and plasma vitamin levels have been used as parameters in the measure of nutritional status and its change.

Measurement of immune competence, measuring total lymphocyte count (TLC), handgrip dynamometry, muscle function testing, and plasma and amino acid patterns have also been used in nutritional status evaluation.

Mullin's prognostic nutritional index (PNI) is also used in attempt to correlate nutritional status with morbidity and mortality.⁴ Shizgal is currently working with isotope dilution techniques to determine total body exchangeable potassium.¹⁰

Methods of studying respiratory quotient with CO₂ and O₂ measurements using the metabolic cart and determining indirect calorimetry are sophisticated modern ways to measure caloric expenditure. However, indirect calorimetry is costly, with present equipment priced at approximately \$50,000, and may therefore not be cost effective for routine hospital use.

The prealbumin test is inexpensive, easy to use, with results obtained within a day, and it is a sensitive test to evaluate changes in nutritional status. Data from several patients at Bridgeport Hospital indicate that it proved to be an excellent marker with results correlated with nutritional progress when proper nutrition was provided. In burn patients it has been found to be the most sensitive marker available.

We have recently become interested in somatomedin-C, a growth factor, as a marker of nutritional status. It appears to correlate well with nitrogen balance with changes in dietary intake.¹¹ Somatomedin-C has been identified as a basic polypeptide identical to insulin-like growth factor 1 (IGF-1). It is considered to be an anabolic hormone having immediate, intermediate, and delayed metabolic effects.

In addition to its effect on DNA and RNA synthesis, somatomedin-C facilitates the transport of glucose and amino acids into cells and the synthesis of glycogen, proteins, and glycosaminoglycans. It stimulates fibroblast activity and endothelial proliferation, and is present in wound fluid. It recently has been studied as a substance necessary for wound healing.¹² There is a need for further studies of somatomedin-C as a nutritional marker. We have reviewed the present status of nutritional support biochemical markers and especially our work with prealbumin marker. There are limited studies in the literature on the use of prealbumin as an effective marker of nutritional status; it is hoped that this report of our experience will stimulate other nutritional support teams to evaluate its use.

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Heavy Drinkers Cost Other Americans Money, but Smokers May Not

Heavy drinking and smoking cause health problems, injuries, property damage, and early deaths that result in higher costs for all Americans. Heavy drinkers cost society more than is taken in from excise taxes on alcoholic beverages, but smokers appear to break even, according to a new study sponsored by the National Center for Health Services Research and Health Care Technology Assessment (NCHSR).

The Rand Corporation study estimates that heavy drinkers—those who drink more than two alcoholic beverages a day—cost society 48 cents for every drink of liquor, glass of wine, or 12-ounce can of beer consumed. This is more than double the average 22 cents tax per ounce of alcohol imposed by Federal and State authorities. Nearly half of the 48 cents represents the loss of life of nondrinkers killed in alcohol-related automobile accidents. Alcohol-related fires, crime, property damage from motor vehicle accidents, medical care for current or former heavy drinkers, sick leave, medical disability, and retirement pension costs account for the rest.

The study also estimates that smokers cost other Americans 15 cents for every pack of cigarettes they smoke over their lifetime. This money is for the higher premiums charged by group health insurance policies in order to pay for smokers' greater use of medical care and for the higher costs of group life and disability insurance premiums, sick leave expenses, and other collectively financed programs. The 15-cent estimate is a net cost, reflecting the difference between costs for smokers' extra medical care, covered work loss, survivors' life insurance benefits, and income tax revenue lost to government—which total 42 cents per pack—and the 27 cents per pack that may be deducted in savings on unneeded nursing home care and pension expenses as a result of smokers' early deaths.

According to the study's leader, Willard G. Manning, Ph.D., who is now with the University of Michigan, the findings suggest that smokers currently may be paying their own way in society because the 15-cent cost per pack they impose on society is less than the average 37 cents imposed on each cigarette pack for excise taxes. However, if the costs of passive smoking were included, the cost to others would rise to 38 cents a pack—about what government collects in excise taxes. In either case, the researchers suggest that making cigarettes more expensive by raising excise taxes might help reduce the number of adolescent smokers.

The findings for heavy drinking and smoking take into account age, sex, race, income, health status, and other factors. The study was based on data from the 1973-77 Rand Health Insurance Experiment and the 1983 supplement to the National Health Interview Survey. The study was conducted under grant HS 05278 from NCHSR. Details are in "The Taxes of Sin: Do Smokers and Drinkers Pay Their Way?" by Dr. Manning, Emmett B. Keeler, Ph.D., Joseph P. Newhouse, Ph.D., Elizabeth M. Sloss, Ph.D., and Jeffery Wasserman, M.S. The article was published in the March 17, 1989 issue of *The Journal of the American Medical Association*.

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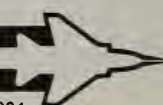
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Important Advances in Clinical Medicine

General and Family Practice

The Scientific Board of the California Medical Association presents the following inventory of items of progress in general and family practice. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers, or scholars to stay abreast of these items of progress in general and family practice that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on General and Family Practice of the California Medical Association and the summaries were prepared under its direction.

Changing Role of Digoxin in Chronic Heart Failure

ALTHOUGH the use of digoxin to control supraventricular tachyarrhythmias is well established, its clinical efficacy in the long-term treatment of congestive heart failure in adults is less clear. Its effectiveness was recently reevaluated compared with placebo in a double-blind trial in patients with mild to moderate heart failure. Digoxin use was shown to increase the ejection fraction and decrease the number of hospital admissions related to heart failure but not substantially affect exercise tolerance or functional class. Digoxin appears to be most useful in patients with greater left ventricular dilatation, greater ejection fraction depression, a third heart sound, and more chronic and severe heart failure. Based on these findings, initiating digoxin therapy for heart failure in patients without atrial fibrillation, enlarged left ventricles, or a third heart sound should be carefully considered.

In patients with stable heart failure and sinus rhythm, the use of digoxin may not be necessary. Several recent studies have shown that digoxin therapy can be withdrawn with minimal adverse clinical or hemodynamic effects in 75% to 100% of patients in this category. The indications for treating patients who have been on long-term digoxin therapy should be reviewed periodically. The history and medical records should be carefully evaluated for definite evidence of previous heart failure. The presence of a third heart sound and a dilated left

ventricle should be elicited on physical examination. In those patients in sinus rhythm whose cardiac status is stable and who have dubious indications for maintenance therapy, drug withdrawal should be considered with careful subsequent monitoring of their clinical state.

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Colposcopy in Human Papillomavirus Infection

IT is likely that most cervical cancer is a sexually transmitted disease caused by the human papillomavirus (HPV). The genital condyloma is the earliest expression of HPV infection. Condyloma must be considered to be the first expression of disease in the cascade of dysplasia—carcinoma in situ—or microinvasive or invasive cervical cancer.

We are in the midst of an epidemic of genital condyloma. It is critical that all family physicians be aware of

the implications and diagnostic techniques required to evaluate their patients, both male and female, for the presence of lesions due to the human papillomavirus.

There are two groups of HPV associated with condyloma. The 6/11 group is usually associated with the classic, arboreal condyloma. Viruses in this group have polypoid mitoses, do not penetrate, and are not incorporated into the host genome. They are not associated with cervical malignancy, although one investigator has implicated them in vulvar malignancy. The etiologic agent of cervical malignancy is considered to be the 16/18 HPV group. Currently identified members of this group are types 16, 18, 31, 33, 35, and 42. These characteristically have aneuploid mitoses, penetrate, and are incorporated into the host genome. Cervical cancer specimens tested with DNA probes have shown the presence of 16/18 HPV virus types 95% of the time. The remaining 5% may represent 16/18 HPV subtypes for which no DNA probe is currently available.

The lesions associated with the presence of the 16/18 HPV are ubiquitous. They are flat and not easily identified by gross inspection. To discover the presence of lesions caused by these viruses, it is necessary to use a colposcope and counterstaining of the cervical, vaginal, vulvar, and possibly perianal or penile tissue with a 5% acetic acid (white vinegar) solution. The condylomatous lesions have an increased nuclear density and amount of keratin. Both the 6/11 and 16/18 groups appear white after vinegar is applied. Occasionally it is helpful to also stain the suspect tissue with Lugol's iodine solution. Iodine will stain areas containing glycogen brown and fail to stain areas devoid of glycogen. The latter are frequently condylomatous lesions.

Often more than one sexually transmitted disease is found in the same patient; therefore, a lesion that is classic for a 6/11 HPV may commonly be found associated with the presence of lesions caused by the 16/18 HPV.

Colposcopy is indicated in the evaluation of all patients with class II findings on Papanicolaou smears that have persisted three or more months and all patients with class III or higher findings. A pathologist's notation of the presence of "koilocytes," a cell classic for the presence of HPV, is also an indication for a patient to be examined colposcopically, as is the presence of a condyloma. As with all sexually transmitted diseases, sexual partners should be advised to seek examination and treatment if one is found to have condylomata. Colposcopy is an easily learned technique that can be incorporated into primary care practice.

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Preventing and Treating Acute Mountain Sickness

ACUTE Mountain Sickness (AMS) is a syndrome characterized by headache, nausea, vomiting, insomnia, and lassitude. The syndrome, part of a continuum including high-altitude pulmonary edema and high-altitude cerebral edema, generally occurs three to eight hours after lowlanders ascend to altitudes greater than 3,000 m (9,800 ft). Because of increased recreational time and improved transportation systems, it is now common for physicians in mountainous areas to see the consequences of altitude illness. The incidence varies with the rate of ascent and the altitude attained. More than 60% of climbers on Mount Rainier (Washington) suffer at least mild AMS. While only 12% of Colorado skiers experience symptoms, AMS causes an estimated annual loss of revenue by the tourist industry of the mountain states of \$50 to \$75 million.

To reduce the incidence and severity of AMS, a graded, staged ascent and a high-carbohydrate diet are recommended. Chemoprophylaxis can also be recommended in certain circumstances where a graded ascent is not possible. The prophylactic use of acetazolamide is usually effective. Possible mechanisms include increased ventilation, metabolic acidosis, improved sleep, the inhibition of cerebrospinal fluid production, diuresis, or a combination of the above. The drug therapy is usually started 12 to 24 hours before ascent and continued for 24 to 48 hours at altitude. Adverse effects include peripheral paresthesias, polyuria, dysgeusia for carbonated beverages, myopia, nausea, and vomiting. Because some of the side effects resemble AMS, some physicians advise trials of the drug at a low elevation before the patient goes to altitude.

Recent studies suggest that the use of dexamethasone is more effective than that of acetazolamide as prophylaxis for AMS symptoms. The mechanism is unknown but probably involves reducing cerebral edema, although antiemetic effects and steroid euphoriant effects may also play a role. Dexamethasone given in a dosage of 12 to 16 mg daily (lower doses are inadequate) starting two to four hours before ascent is recommended. Stopping the therapy before acclimatization takes place may result in rebound altitude illness. The use of dexamethasone for AMS prophylaxis is not without its risks and should be limited to special circumstances because of inadequate experience, the severity of possible side effects including acute psychosis and drug withdrawal, and the benign nature of AMS in most cases. Current recommendations generally limit the use of dexamethasone for AMS pro-

phylaxis to persons making forced, rapid ascents to high altitude for a short stay and with a guaranteed retreat route, thereby avoiding the risk of drug withdrawal.

The treatment of choice for all forms of high-altitude illness is descent. Mild forms of the illness, however, may not mandate descent, or descent may be impractical, and the clinician may wish to try other methods. Mild AMS can be treated by waiting for further acclimitization at the same altitude. Administering analgesics, prochlorperazine, or acetazolamide may provide symptomatic relief. If the symptoms progress, descent is mandatory. For moderate to severe AMS (early cerebral edema), descent should be attempted if possible. The administration of dexamethasone, 4 mg every six hours, is probably indicated. A prompt response (four to eight hours) is expected. This drug therapy must be continued for 48 hours, then tapered or continued until the victim has descended or acclimitized.

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Evaluating Palpable Breast Lumps with Negative Mammography

BREAST cancer is an increasingly important problem in health care. Much is written about screening and diagnostic measures. It is important to realize that when a breast lump is present, a normal mammogram does not preclude the need for biopsy to establish the diagnosis.

It has been well established that mammography is important in screening for breast cancer. Authorities generally agree that mammography is more accurate than palpation at finding minimal breast lesions. This was borne out in studies at breast cancer detection centers in Milwaukee and Cincinnati. In its present state of development, however, mammography will yield a certain percentage of falsely normal results (false-negatives). There are several reasons for this: subtle or absent signs in some lesions (in situ and intraductal lesions may show no obvious radiographic patterns), difficult-to-detect locations such as near the chest wall or in the tail of the breast, and inaccurate reading. The likelihood of a false-negative mammogram is increased in patients with small breasts, dense breasts, and with retroareolar lesions. Using Wolfe's classification, the likelihood of a cancer

being missed in a fatty (N_1) breast is only 2.08% but rises to 56.25% in a very dense (P_2) breast.

Thus when there is a suggestive, palpable breast lump, the patient cannot be safely followed by observation, repeated palpation examinations, and periodic mammograms. In such a patient, a definitive diagnosis must be established by examining a tissue specimen. The tissue specimen can be obtained by excisional biopsy and pathologic diagnosis, or, in selected circumstances, cells obtained by thin-needle aspiration for cytologic diagnosis. Only then will the risk of a normal mammogram giving a false sense of security be avoided.

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Asymptomatic Bacteriuria During Pregnancy

SIGNIFICANT bacteriuria in asymptomatic pregnant women was defined by Kass in 1960 as greater than 10^5 organisms per milliliter of clean-voided urine. The prevalence of asymptomatic bacteriuria during pregnancy is 2% to 14%. Factors associated with a higher risk include advanced age, higher parity, and a lower socioeconomic status. In approximately 20% to 40% of untreated women with asymptomatic bacteriuria, a symptomatic urinary tract infection, such as cystitis or pyelonephritis, will subsequently develop during the course of pregnancy or immediately postpartum. Conversely, acute pyelonephritis will develop in less than 5% of patients with asymptomatic bacteriuria who have been appropriately treated with antibiotics.

The basic factor predisposing to urinary tract infection during the prenatal period is the relative stasis of urine caused by pregnancy-induced changes. Hydroureter is common during the last half of pregnancy. Progesterone causes the ureters to dilate, while the enlarging uterus leads to mechanical compression. In addition, changes in a pregnant woman's immune system may make her more susceptible to infection.

Escherichia coli accounts for about 80% of the identified pathogens. *Klebsiella pneumoniae*, *Proteus mirabilis*, and *Enterobacter* organisms are also common infecting organisms.

Several investigators have found an increased incidence of premature delivery in untreated patients with asymptomatic bacteriuria. Patients who are treated and remain unaffected, however, do not appear to be at

increased risk for preterm delivery. The patients at highest risk are those in whom acute pyelonephritis develops, with associated premature labor and advanced cervical dilation.

While urine culture is considered the gold standard for diagnosing urinary tract infections, other methods have been proposed as cost-effective means for screening obstetric patients for asymptomatic bacteriuria. Routine urine analysis, Gram's stain, and chemical analysis to test for leukocyte esterase and nitrite have not been proved sufficiently sensitive. The dip-slide (Uricult) test has been valuable in the ambulatory setting. If there is growth on the MacConkey agar side of the paddle (specific for the growth of gram-negative bacilli) at a colony count of 10^4 or more, a positive traditional culture can be expected 81% of the time. This is the predictive value of the positive result. It is judicious to then also do routine culture and sensitivity testing. If there is growth on the cysteine-lactose-electrolyte-deficient agar side of the paddle (which supports the growth of all organisms) at a colony count of 10^5 or more, culture before treatment is necessary because of the high percentage of false-positives. Recently a test known as the FiltraCheck-UTI bacteriuria detection system has been evaluated. This makes use of a growth-independent colorimetric method that uses stable reagents and a disposable filter disk. It is inexpensive and can be done in one minute. Initial results have shown a sensitivity of 96.5% and a specificity of 79.7%. It may be useful in the future as an initial screen for asymptomatic bacteriuria.

Because the most commonly identified organism is *E coli*, current treatment recommendations include administering an antimicrobial drug for 7 to 14 days, such as ampicillin, nitrofurantoin, sulfonamides (except in the third trimester), or first-generation cephalosporins. The efficacy of a single-dose therapy for asymptomatic bacteriuria during pregnancy has been confirmed, with the eradication of bacteria in 70% to 80% of cases. Recurrence rates are less than 5%. The advantages of single-dose therapy include greater patient compliance, lower cost, fewer side effects, and less potential hazard to the fetus. This regimen is most appropriately used in women for whom the above factors are significant and who have not had urologic problems. A culture should be repeated at the completion of therapy, and patients with a positive result need to be re-treated. It has been recommended that patients treated for acute pyelonephritis be placed on suppressive antibiotic therapy or have regular repeat cultures for the duration of their pregnancy.

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Lyme Disease

FIRST described in November 1975, Lyme disease has become the most common tick-borne disease in the United States. The disease is transmitted by the bite of a tick, *Ixodes dammini*, although only a few patients will recall the tick bite. In 1984 the causative organism of Lyme disease was identified to be a *Borrelia burgdorferi*.

Lyme disease indiscriminately affects both sexes and all age groups of patients and most often occurs between June and September. The disease occurs predominantly in three regions in the US—the coastal Northwest; Minnesota and Wisconsin; and parts of California, Oregon, Utah, and Nevada.

Lyme disease occurs in three distinct clinical stages. Stage I is characterized by a rash, erythema chronicum migrans, which develops 2 to 30 days after inoculation by the tick bite. This rash occurs in 60% of patients and is often accompanied by profound fatigue, low-grade fever, chills, stiff neck, arthralgias, and myalgias. The second stage of disease occurs in only 15% of patients and includes neurologic and cardiac symptoms. Stage III occurs weeks to years after the initial infection and consists of polyarthritis that is clinically similar to rheumatoid arthritis. This arthritis will develop in about 60% of patients who have not received appropriate treatment of stage I or II.

The treatment of choice for Lyme disease is to administer tetracycline, 250 mg four times a day for ten days. Children younger than 8 years may be given penicillin, 50 mg per kg body weight per day, or erythromycin, 30 mg per kg per day for ten days. The symptoms may worsen immediately following the initiation of antibiotic therapy, indicating the Jarisch-Herxheimer reaction. Early recognition and treatment can substantially reduce the incidence and severity of the arthritis associated with stage III disease.

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Prenatal Evaluation for Hepatitis B Surface Antigen

EACH year 3,500 newborns become hepatitis B virus carriers following the perinatal transmission of hepatitis B virus infection. Hepatitis B is easily transmitted during pregnancy, and most infected newborns (85% to 90%) will become long-term carriers.

At-risk newborns treated early have an 85% to 95% reduction in the carrier rate. Unfortunately, risk factor screening identifies only 35% to 65% of hepatitis B virus carriers, and risk factors are not consistently applied in practice. In response to these difficulties and in light of the substantial morbidity of hepatitis B in newborns, the Immunization Practices Advisory Committee (ACIP) of the Centers for Disease Control now recommends that all prenatal patients be screened for hepatitis B virus infectivity.

The ACIP recommends that testing for the hepatitis B surface antigen be added to the laboratory tests done on the first prenatal visit. Women testing negative should be re-screened if involved in high-risk behaviors during pregnancy, such as intravenous drug use. Women testing positive should be considered carriers and their newborns treated.

Once the hepatitis B surface antigen is identified in a patient, the following actions should occur:

- If there is evidence of acute or chronic liver disease, additional therapy may be indicated for the woman.
- Household contacts and sexual contacts need to be screened, and, if susceptible, prophylactic treatment (hepatitis B vaccine) needs to be instituted.
- The newborn infant will need to be treated as follows: hepatitis B immune globulin, 0.5 ml, is given intramuscularly when the infant is stable (within 12 hours, if at all possible); hepatitis B vaccine, 0.5 ml, is given intramuscularly at a separate site at the same time as the hepatitis B immune globulin, and repeat doses are given at 1 and 6 months of age; the child should have hepatitis B surface antigen and antibody testing at 12 to 15 months of age to assure effectiveness of the treatment.

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Preventing Teenaged Addiction to Tobacco

TOBACCO abuse is the most important preventable cause of illness and death in our society. The highly addictive nature of tobacco was well documented by the most recent Surgeon General's report. Cessation pro-

grams are certainly worthwhile but have shown limited success in treating addiction. The primary prevention of tobacco abuse therefore seems to hold greater promise for controlling the tobacco pandemic.

Few people begin to smoke after reaching adulthood. In fact, 60% of all smokers start using tobacco by the age of 14 years, and 90% start by the age of 19. It is therefore logical to direct preventive efforts at children and adolescents.

Each year our children are bombarded with \$2 billion worth of advertising that attempts to associate tobacco use with "coolness," sexiness, athletics, and the attainment of adulthood. In a highly successful effort to make chewing tobacco more attractive to children, one company markets little teabaglike packets of candy-flavored snuff. Once addicted, teenaged boys are likely to become lifelong consumers of tobacco products.

These Madison Avenue techniques cannot be effectively countered with scare tactics—a 14-year-old boy is seldom impressed by the fact that his smoking now may cause lung cancer when he is 60. On the other hand, humor and parodies of tobacco ads are apparently more effective in countering the promotion of tobacco. The goal is to "laugh the pushers out of town," while explaining the harmful effects of tobacco in terms to which children can relate: "Smoking gives you yellow teeth and bad breath and makes you *less* attractive to the opposite sex." "Smoking doesn't make you 'cool'—only 'nerds' smoke cigarettes or dip snuff." "Tobacco is a 'rip-off,' and money that kids waste on tobacco could be spent on clothes and records instead."

Physicians can cooperate with local school districts to develop tobacco education curricula for fifth- to seventh-grade students. A model program is available from DOC (Doctors Ought to Care, 1423 Harper St, Augusta, GA 30912), with lesson plans for several teacher-conducted sessions, followed by a slide presentation by a physician. The program culminates in a poster contest, with the winning student's poster displayed as a billboard in a prominent location in the community.

Tobacco companies spend millions of dollars to sponsor sporting events, circumventing the regulations that prohibit the explicit advertising of tobacco products on television. Through the sponsorship of sports, they attempt to establish an association between tobacco and athletic prowess and to buy an aura of respectability. Although the industry denies it, much of this sports-related tobacco advertising appears to be directed at youth. Some communities have responded with parodies such as the "Emphysema Slims Tennis Tournament" and the "Dead Man Chew Softball Tournament." Others have used paid counteradvertising on television, radio, billboards, and bus benches to tell the truth about tobacco and to point out the insidious techniques used in its promotion.

These new approaches for preventing tobacco abuse by children have been pioneered by DOC. The American Medical Association, the American Academy of Family Physicians, and the American Cancer Society are all

beginning to adopt these new methods, while continuing their efforts to encourage smoking cessation.

Through counteradvertising and tobacco education programs on the local and national levels, it may be possible to reduce the number of new smokers and thereby decrease the impact of the tobacco-related diseases that presently kill 1,000 Americans every day.

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The World Cigarette Pandemic, *NY State J Med* 1983 Dec (special issue [available as Blum A(Ed): The Cigarette Underworld, Secaucus, NJ, Lyle Stuart, 1985]).

Tobacco and Youth Reporter, STAT (Stop Teenage Addiction to Tobacco), PO Box 50039, Palo Alto, CA 94303.

Diarrhea in Children

FOR many clinicians, the treatment of diarrhea is straight-forward: the patient is not given anything orally while the intravenous (IV) administration of fluids is started, then the patient is given clear liquids for 24 to 48 hours, followed by a BRAT—bananas, rice, apple-sauce, toast—diet. Recent studies, primarily in third-world populations, have shown that this is not the optimal therapy.

Perhaps the biggest change has been in IV fluids therapy, which is now recognized as rarely necessary. Instead, oral rehydration solutions—World Health Organization Oral Rehydration Solution (WHO ORS), Pedialyte, Lytren—are available and effective in replacing lost fluids. It should be emphasized that many “clear liquids” such as soft drinks and popsicles are not ideal therapies: they are low in sodium and potassium, key electrolytes in this disease state, and high in carbohydrates, a fact that may prolong the diarrhea. If soft drinks or fruit juices are used, they should be diluted one part beverage to two parts water because they are hyperosmolar and may draw water into the lumen. In addition, commercially prepared soup (high in salt content) and tap water (no electrolytes) should not be a major component of the therapy. For these reasons, many clear liquids should be avoided, except in limited quantities or in mild cases.

Because continued breast-feeding is beneficial, there is a growing thought that the disease state responds better to the additional nutrition than to starvation. In under-developed countries where no IV fluids are available and the WHO ORS formula is widely used, research has shown that replacing the glucose in the oral rehydration solution with rice powder or protein actually decreases the recovery time. Recent studies in England and the United States have confirmed these findings. Thus, the trend is now to give oral clear liquids (as described above) in the first few hours of illness followed by early

feeding of a carbohydrate-protein-electrolyte mixture while the patient still has diarrhea. This regimen is thought to be not only safe but preferred because it decreases morbidity and costs.

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Hamilton JR: Viral enteritis. *Pediatr Clin North Am* 1988;35:89-101.

Santosham M, Foster S, Reid R, et al: Role of soy-based, lactose-free formula during treatment of acute diarrhea. *Pediatrics* 1985; 76:292-8.

Circumcision Reevaluated

DESPITE being the most common surgical procedure in the country, circumcision has been the center of tremendous and often intense debate for the past 40 years. So adamant have the two camps been that little consensus has been achieved. Thus, though the American Academy of Pediatrics is reevaluating its 18-year-old antircircumcision stance, it is unlikely the controversy will be resolved. Though there are currently no answers, family physicians should be updated on the debate in order to better inform parents and to assist in the needed research.

Central to the debate is the evaluation of health risks and benefits. Most health risks of remaining uncircumcised—balanitis, posthitis, penile cancer, phimosis, and foreskin trauma—are too insubstantial in frequency or morbidity to play a role in decision making. The recently discovered ten-fold increase in urinary tract infections in uncircumcised persons has swayed many to favor the procedure, but the long-term effects of this increased risk are not known. In addition, the original belief that the procedure is “harmless” in most infants has come into question with the recent realization that neonates do feel pain and show pronounced physiologic and biochemical changes to this pain.

What role, then, does the family physician have? It is clear there is no consensus, and the field is evolving. To strongly adhere to one belief or the other is probably unwise. Until such time that the several questions regarding circumcision and the uncircumcised state are answered, supportive counseling of parents is the best plan.

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The Melanoma Epidemic

ALTHOUGH the epidemic of disease mediated by the human immunodeficiency virus has rightfully taken much of our attention, primary care physicians must not forget that we are also in the midst of an epidemic of malignant melanoma. The incidence of malignant melanoma roughly tripled between 1950 and 1970 and has increased by 700% over the past 55 years. It is estimated that by the turn of the century malignant melanoma might well afflict 1% of the general American population.

It is extremely important that primary care physicians be trained to diagnose malignant melanoma in its early stages because prognosis is best correlated with the thickness of the lesion. The relationship of melanoma thickness to five-year survival is as follows: 0 to 0.85 mm, 99%; 0.86 to 1.69 mm, 94%; 1.70 to 3.59 mm, 81%; and 3.60 mm or larger, 49%.

Definite risk factors for melanoma include white race, particularly those of Celtic heritage; sun exposure, particularly with episodes of sunburn; dysplastic nevi, particularly familial dysplastic nevi; and large congenital nevi (greater than 20 cm).

Patients should be encouraged to report any change in a skin lesion, particularly recent growth, bleeding, pain, or the development of a new lesion. Physicians should remove or take a biopsy of any skin lesion that is at all suggestive of melanoma.

Physicians should be vigilant in screening for melanoma and should keep in mind the rule of "ABCD": *A*symmetry, *B*order irregularity, *C*olor variegation, and *D*iameter generally greater than 6mm. Various textbooks and monographs are available to assist physicians in recognizing melanoma in its earliest stages.

The familial dysplastic nevus syndrome is an autosomal dominant condition with a lifetime incidence of melanoma approaching 100%. Dysplastic nevi tend to be more plentiful (25 to 75 per person) and larger (6 to 15 mm) than common nevi. Dysplastic nevi are acquired after birth and often have irregular borders, variegated colors (particularly tan, brown, and pink), and indistinct borders fading into the adjacent normal skin.

Primary prevention includes avoiding sunlight, using protective clothing and hats, and using sunscreens as early as infancy and throughout adult life. Sunbathing and the use of tanning parlors should be actively discouraged. The melanoma epidemic is presenting all primary care physicians with the challenge of the primary prevention of the disease and the early detection of melanoma at a time when it is completely curable.

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Silent Myocardial Ischemia

ALTHOUGH myocardial ischemia and infarction are major health problems in the western world, our understanding of this disease remains incomplete. Physicians think of ischemic heart disease as a clinical syndrome manifested by chest pain or other "anginal equivalents." The cardiologic literature over the past decade has clearly shown, however, that silent myocardial ischemia is a common manifestation of coronary artery disease. In fact, there is every reason to think that silent myocardial ischemia carries the same (or worse) clinical significance as symptomatic coronary artery disease. This should come as no surprise because one of five sudden death victims in the United States has no history of heart disease, yet commonly has evidence of advanced arteriosclerotic disease in the coronary arteries at autopsy.

Silent myocardial ischemia has been studied predominantly using two tools: ambulatory Holter electrocardiographic monitoring and the exercise test. Although factors that make myocardial ischemia painless in some persons are not completely understood, it is a common phenomenon. In a study of patients with angina with known coronary artery disease documented by arteriography, 75% of all ambulatory episodes of ischemia were painless. Silent myocardial ischemia shares the same circadian variations as angina pectoris and myocardial infarction, occurring most often in the morning, generally between 0600 and 1200. Silent myocardial ischemia, however, seems to develop more commonly at rest and at lower levels of heart rate and blood pressure. This suggests, but does not prove, that silent myocardial ischemia may be due to enhanced coronary artery vasoconstriction, as opposed to an increase in myocardial oxygen demand.

Although it is becoming clear that the problem of silent myocardial ischemia is one of major proportions, the solution is less clear. Cohn recommends screening exercise tests in all patients with two or more major risk factors for coronary artery disease, particularly those with diabetes mellitus because of visceral neuropathy. Patients with abnormal results on treadmill tests, but ST depression less than 2 mm in stage I or II of the Bruce protocol, should have radionuclide imaging. The decision to proceed to coronary arteriography depends on the patients. In general, patients suffering a myocardial infarction undergo exercise testing, usually at least two to three weeks after the infarction. Silent myocardial ischemia in patients with stable angina pectoris is often best detected by ambulatory Holter monitoring.

Currently there is no reason to treat silent myocardial ischemia any differently than symptomatic angina pectoris. Risk factors should be modified to the extent possible. The decision to proceed to arteriography and ultimately angioplasty or coronary artery bypass grafting must be tailored to each patient. In patients who have

suffered a myocardial infarction and subsequently show silent myocardial ischemia, many data suggest a long-term benefit with β -blocker therapy. Patients with angina pectoris and silent myocardial ischemia are subject to vasospasm and therefore may benefit from using calcium channel blockers, as well as nitrates and β -blockers.

In the forthcoming years, much new information will surface regarding silent myocardial ischemia. Because of the extent of this public health problem, primary care physicians should make every effort to keep abreast of new developments in the diagnosis and treatment of the disorder.

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- Cohn PF, Kannel WB: Recognition, pathogenesis, and management options in silent coronary artery disease: Introduction. *Circulation* 1987;75(pt 2):111.

Fluoroquinolones

THE fluoroquinolones are a remarkable new group of bactericidal antibiotics related to nalidixic acid. Among other effects, they appear to act on DNA gyrase, an enzyme involved in DNA replication. The agents currently available in the United States include norfloxacin and ciprofloxacin. Because these agents show a wide spectrum of bactericidal activity and an apparently excellent safety profile, they can be extremely effective agents in a primary care practice but must be used wisely.

The spectrum of antibacterial activity of these agents includes *Escherichia coli*, *Klebsiella*, *Hemophilus influenzae* (including ampicillin-resistant strains), meningococci, *Branhamella catarrhalis*, *Salmonella*, *Shigella*, *Campylobacter jejuni*, *Aeromonas*, *Yersinia enterocolitica*, staphylococci (including methicillin-resistant *Staphylococcus aureus*), and *Pseudomonas aeruginosa*.

Norfloxacin and ciprofloxacin have been shown to be effective for the treatment of genitourinary and gastrointestinal tract infections, uncomplicated gonorrhea, prostatitis, and as prophylactic agents against travelers' diarrhea and gram-negative infections in patients with neutropenia. The fluoroquinolones should not be used to treat anaerobic infections, and their usefulness in a variety of other situations, particularly infections of the central nervous system, is unknown.

Adverse effects of the fluoroquinolones have been predominantly mild—nausea, vomiting, abdominal pain, dizziness—but neutropenia and elevated serum aminotransferase levels have been reported. Rare episodes of seizures and reversible arthropathy have been reported with these agents. The use of fluoroquinolones is not recommended for patients younger than 17 years or pregnant or breast-feeding women.

Primary care physicians should resist the temptation to use the fluoroquinolones as "shotgun" therapy for various outpatient infections. Where possible, particularly in uncomplicated genitourinary tract infections, older and cheaper agents, such as the sulfonamides and penicillins, should be used. Because the development of bacterial resistance to an antibiotic is directly proportional to its use, the fluoroquinolones should be reserved for cases in which they clearly show superiority to conventional agents. Also, primary care physicians must be vigilant of the possibilities of serious adverse effects, particularly central nervous system toxicity and arthropathy.

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- Wolfson JS, Hooper DC: Norfloxacin: A new targeted fluoroquinolone antimicrobial agent. *Ann Intern Med* 1988; 108:238-51.

Posttraumatic Stress Disorder in Southeast Asian Refugees

SINCE 1975 more than 700,000 refugees from Southeast Asia have immigrated to the United States. The largest number of these have settled in California. Initial health care focused on infectious disease considerations of hepatitis, parasitology, and diseases endemic in the third world. Further evaluation revealed a substantial difference between the better educated, more highly skilled refugees in the first wave of immigration in 1975 to 1978 and the second wave of war refugees in 1978 to 1979. In the past five years, researchers at several mental health clinics focusing on refugee psychiatric problems have begun to record the previously undetected extent of significant psychological problems in this population. Mollica and co-workers in Boston, Westermeyer in Minnesota, and Kinzie and Fleck in Portland, Oregon, in particular, have reported the extent and severity of depression and posttraumatic stress disorder in Southeast Asian refugees, particularly those in the second wave of immigration. They have also reported that the Cambodian refugees who suffered some of the atrocities of the Pol Pot regime appeared to be the most severely affected.

These researchers have been working primarily in mental health centers designed for refugee health care. They all comment, however, on the consistent pattern of somatization in Southeast Asian refugees and the cultural inhibition in identifying mental health problems. Therefore, refugees are more likely to present to primary care physicians than to mental health services. Unless family physicians and internists are alert to the symptoms of posttraumatic stress disorder, the diagnosis may be missed. The symptom complex of the disorder includes flashbacks, nightmares, severe difficulty concentrating,

panic attacks, strong startle responses, emotional blunting, and extreme avoidance of stimuli that induce memories of the traumatic experiences. The somatic presenting complaints are frequently headaches, dizziness, and abdominal, back, or joint pain.

With more culturally aware assessments, primary care physicians can play a key role in determining the prevalence of this problem, in mobilizing appropriate consultation and community resources, and in minimizing the iatrogenic risks of multidrug therapy and unnecessary diagnostic evaluations. They may also be better able to establish supportive continuing relationships with these patients, who tend to drift from physician to physician seeking relief for their various somatic complaints. Only with continuity will it be possible to help Southeast

Asian refugees begin to understand and grapple with this complex disorder.

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Lyme Disease: An Annotated Bibliography

Editor's Note: This annotated bibliography on the diagnosis, clinical manifestations, and treatment of Lyme disease is reprinted with the permission of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (AMS) Information Clearing House. The bibliography reprinted here is one section from the recently published *Lyme Disease: An Annotated Bibliography*, which contains 133 citations of patient and professional education materials; most have been published since 1984. Its purpose is to provide information sources for physicians, nurses, other health professionals, and patients and their families regarding the nature, diagnosis, and treatment of these disorders. These information sources include brochures, book chapters, and technical state-of-the-art review articles. An author index and a subject index are provided. Each citation includes an abstract, information on the source of the material, its availability and price, and, when applicable, the number of references cited in the article. To obtain *Lyme Disease: An Annotated Bibliography*, send a check for \$5.00 payable to AMS Clearinghouse to:

National Arthritis and Musculoskeletal and Skin Diseases
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Diagnosis, Clinical Manifestions, and Treatment

Barbour, A.G.

"Laboratory Aspects of Lyme Borreliosis."

Clinical Microbiology Reviews, 1(4): 399-414. October 1988.

This review article describes the clinical history, immune response, symptoms, and tissue pathology of Lyme disease. Direct detection and in vitro and in vivo cultivation of the spirochete is described in technical detail. Total serum IgM correlates well with the degree of disease activity. The specific antibody response is measured through indirect immunofluorescence studies such as IFA and ELISA that recognize *B. burgdorferi* antigens. There may be false positive results with spirochetal diseases such as syphilis and relapsing fever, and Western blot tests which differentiate between the different spirochete antigens help in the diagnosis. (178 references)

Berardi, V.P.; Weeks, K.E.; Steere, A.C.

"Serodiagnosis of Early Lyme Disease: Analysis of IgM and IgG Antibody Responses by Using an Antibody-Capture Enzyme Immunoassay."

Journal of Infectious Diseases, (158) (4): 754-760. October 1988.

The authors used an antibody-capture enzyme immunoassay (EIA) to evaluate the early antibody responses to *Borrelia burgdorferi* in paired sera from 30 patients with erythema migrans. During acute disease, 20 (67%) patients had elevated specific IgM responses, and by convalescent (one to four weeks after treatment), 28 (93%) patients had increased IgM or IgG responses. In acute specimens, elevated IgM responses correlated with disseminated infection; however, by convalescence, most patients with either localized or disseminated disease had positive tests. Among 133 control subjects, IgM cross-reactivity was observed in four of 37 patients with either Epstein-Barr virus or rickettsial infections, and false-positive IgG tests were seen in eight of 28 patients with syphilis. With antibody-capture EIA, the diagnosis of Lyme disease can be confirmed in the majority of acutely ill patients

and in almost all patients by convalescence. (22 references)

Berger, B.W.

"Treating Erythema Chronicum Migrans of Lyme Disease."

Annals of the New York Academy of Sciences, 539: 346-351. August 16, 1988.

Between June 1981 and July 1987 the efficacy of antibiotic treatment of 215 patients with erythema chronicum migrans of Lyme disease was evaluated in terms of the necessity for retreatment and the prevention of the late manifestations of Lyme disease. The principal antibiotics utilized to treat 161 patients through 1986 were varying doses of tetracycline, or penicillin alone or in combination with probenecid. Two of 80 patients with a minor form of the illness and 17 of 81 patients with a major form of the illness required retreatment. There were four patients who did not respond to retreatment with their original medication. A 15 to 30-day course of amoxicillin (500 mg q.i.d.) and probenecid (500 mg q.i.d.) or doxycycline (100 mg t.i.d.), and on three occasions ceftriaxone (2-4 g/day i.v.), were used to treat 54 patients in 1987. Although it is too early to judge the efficacy of treatment of these patients, increases in the incidence of Herxheimer reactions and drug eruptions were observed. Strict compliance with treatment protocols and the possibility of reactions to medications should be thoroughly discussed with patients. (26 references)

Clark J.R. et al

"Facial Paralysis in Lyme Disease."

Laryngoscope, 95 (11): 1341-1345. November 1985.

This paper reviews the clinical course, distinguishing features, and outcome of 124 palsies associated with Lyme disease in 101 patients seen between 1975 and 1984. Unilateral and bilateral facial paralysis may occur in up to 11% of patients with Lyme disease. The 99.2% spontaneous recovery rate demonstrates the unequivocally excellent prognosis of this palsy and confirms that operative intervention is not indicated. The otolaryngologist should consider this etiology in all otherwise idiopathic facial paralyses, especially when presenting in summer months in endemic areas, or when bilateral. Positive Lyme disease spirochete titers are helpful in the diagnosis. The authors believe antibiotics should be given to patients with this facial palsy in order to treat any other concurrent manifestations of the illness and to prevent subsequent complications. (15 references)

Costello, C.M.; Steere, A.C.; Pinkerton, R.E.; Feder, H.M.

"A Prospective Study of Tick Bites in an Endemic Area for Lyme Disease."

Journal of Infectious Diseases, 159 (1): 136-139. January 1989.

In field studies in endemic areas, the spirochetal pathogen for Lyme disease has been found in 10% to 35% of ixodid ticks and on Shelter Island, New York, greater than 50% of ticks have been infected with this organism. Because infection rates in ticks are high, primary care physicians are then faced with the dilemma of whether to treat patients bitten by these ticks immediately or to wait and treat them only if the symptoms of Lyme disease develop. Currently, the risk-benefit ratio of disease prevention versus adverse effects of unnecessary antimicrobial therapy is unknown. To address this question, the authors conducted a double-blind, placebo-controlled trial of penicillin prophylaxis in patients bitten by *I. dammini* ticks in an endemic area for Lyme disease. They found that the risk of acquiring Lyme disease from recognized tick bites was less than one would expect from the infection rate in ticks.

From the National Institute of Arthritis and Musculoskeletal and Skin Diseases, Bethesda, MD.

(15 references)

Dattwyler, R.J.; Halperin, J.J.; Pass, H.; and Luft, B.J.

"Ceftriaxone as Effective Therapy in Refractory Lyme Disease."
Journal of Infectious Diseases, 155 (6): 1322-1325. June 1987.

Studies have shown that appropriate antibiotic therapy early in the course of *Borrelia burgdorferi* hastens the resolution of erythema chronicum migrans (ECM) and can prevent progression of the disease. The most effective established treatment of late Lyme disease is high-dose, intravenous penicillin. The authors believe that ceftriaxone is a more effective treatment for the chronic stages of Lyme disease because it has a low incidence of side effects, good tissue penetration (particularly into the CNS), and the ability to kill *B. burgdorferi* at easily obtainable in vivo concentrations. (24 references)

Dattwyler, R.J. and Halperin, J.J.

"Failure of Tetracycline Therapy in Early Lyme Disease."
Arthritis and Rheumatism, 30 (4): 448-450. April 1987.

This article describes the clinical courses of five patients with Lyme disease who developed significant late complications despite receiving tetracycline early in the course of their illness. All five patients had been treated for erythema chronicum migrans with a course of tetracycline that met or exceeded current recommendations. The late manifestations of Lyme disease included arthritis, cranial nerve palsy, peripheral neuropathy, chronic fatigue, and changes in mental function. The authors' findings suggest that the use of tetracycline at a dosage of 250 mg four times a day for 10 days, as a treatment for early Lyme disease should be reconsidered. To determine optimal therapy for early Lyme disease, a study that compares an increased dosage of tetracycline with alternative treatments is indicated. (21 references)

Dattwyler, R.J. et al

"Seronegative Lyme Disease. Dissociation of Specific T- and B-Lymphocyte Responses to *Borrelia burgdorferi*."
New England Journal of Medicine, 319 (22): 1441-1446. December 1, 1988.

The diagnosis of Lyme disease often depends on the measurement of serum antibodies to *Borrelia burgdorferi*, the spirochete that causes this disorder. Although prompt treatment with antibiotics may abrogate the antibody response to the infection, symptoms persist in some patients. The authors studied 17 patients who had presented with acute Lyme disease and received prompt treatment with oral antibiotics, but in whom chronic Lyme disease subsequently developed. Although these patients had clinically active disease, none had diagnostic levels of antibodies to *B. burgdorferi* on either a standard enzyme-linked immunosorbent assay or immunofluorescence assay. On a Western blot analysis, the level of immunoglobulin reactivity against *B. burgdorferi* in serum from these patients had a vigorous T-cell proliferative response to whole *B. burgdorferi*, with a mean ($\pm$ SEM) stimulation index of 17.8 ± 3.3 , similar to that (15.8 ± 3.2) in 18 patients with chronic Lyme disease who had detectable antibodies. The T-cell response of both groups was greater than that of a control group of healthy subjects (3.1 ± 0.5 ; $p < .001$). The authors conclude that the presence of chronic Lyme disease cannot be excluded by the absence of antibodies against *B. burgdorferi* and that a specific T-cell blastogenic response to *B. burgdorferi* is evidence of infection in seronegative patients with clinical indications of chronic Lyme disease. (49 references)

Dattwyler, R.J.; Halperin, J.J.; Volkman, D.J.; Luft, B.J.

"Treatment of Late Borreliosis: Randomized Comparison of Ceftriaxone and Penicillin."
Lancet, 1 (8596): 1191-4. May 28, 1988.

Twenty-three patients with clinically active late Lyme disease were randomly assigned to intravenous treatment with either penicillin or ceftriaxone. Of the 10 treated with penicillin, five were judged treatment failures; of the 13 who received ceftriaxone, only one did not respond. An additional 31 patients were subsequently treated with ceftriaxone 4 g/day ($n=17$) or 2 g/day ($n=14$); success rates in both groups were comparable to those in the cohort randomized to ceftriaxone. Patients unresponsive to ceftriaxone were more likely to have received corticosteroid treatment. (32 references)

Dotevall, L.; Alestig, K.; Hanner, P.; Norkrans, G.; Hagberg L.

"The Use of Doxycycline in Nervous System *Borrelia burgdorferi* Infection."

Scandinavian Journal of Infectious Diseases, 53 (Supplement); 74-79. 1988.

Alternatives to high dose benzylpenicillin treatment are sought for in patients with mild *Borrelia burgdorferi* nervous system infection. Doxycycline 100 mg twice daily for 10-20 days was used in nine patients with radicular pains, vertigo, or weakness in the legs caused by *B. burgdorferi* infection. The patients had suffered from neurologic symptoms for a median time of five months. In eight patients doxycycline was orally administered and in one intravenously. All nine patients had remission of radicular pain and vertigo during the treatment period. The doxycycline concentration in the cerebrospinal fluid was 0.2-1.0 mg/l and in serum 1.9-7.1 mg/l after five days treatment. Doxycycline treatment was found successful in our patients with mild tick born neuroborreliosis. (24 references)

Duffy, J. and Mertz, L.E.

"Serologic Testing for Lyme Disease" (editorial).
Annals of Internal Medicine, 103 (3): 458. September 1985.

Until recently, laboratory studies available to practicing physicians were not specific and thus were of limited value in contributing to a definitive diagnosis of Lyme disease. Recovery of the spirochete from some human specimens and its demonstration in tissue are possible, although not practical in studies reported to date. In the past two years, however, the laboratory has assumed a greater role in diagnosis. Although serologic testing is sound, the authors stress several caveats. Test results must always be interpreted in the context of the illness. In patients with Lyme disease, elevated antibody titers may be delayed or absent, particularly in those with limited manifestations and in recipients of antibiotics that can abrogate the antibody response. On the other hand, false-positive results may occur in sera from patients with other treponemas infections or certain autoantibodies. (7 references)

Duray, P.H.; Steere, A.C.

"Clinical Pathologic Correlations of Lyme Disease by Stage."
Annals of the New York Academy of Sciences, 539: 65-79. August 26, 1988.

Lyme disease is capable of producing a wide variety of clinical pathologic conditions and lesions having in common histologic features of collagen-vascular disease. The plasma cell is an omnipotent inflammatory responder in most tissues involved by Lyme disease, ranging from relatively acute to lesions that have gone on for years. Vascular thickening also seems to be prominent, and in the dermis is accompanied by scleroderma-like collagen expansion. The disease in some ways resembles the responses seen in lupus erythematosus such as mild cerebritis with lymphocytes and plasma cells in the leptomeninges. Lymphoplasmacytic panniculitis of Lyme disease resembles lupus profundus, both in the infiltrate and the plasma cell-blood vessel relationship. The onion skin thickened vessels of the synovia resemble the vessels of lupus spleens, while the sclerodermoid thickening of the dermis and various skin lesions of stage III Lyme disease suggest a collagen-vascular disorder. Finally, the perivascular lymphoid infiltrate in clinical myositis does not differ from that seen in polymyositis or dermatomyositis. All of these histologic derangements suggest immunologic damage in response to persistence of the spirochete, however few in number. (30 references)

Eichenfield, A.H.

"Diagnosis and Management of Lyme Disease."
Pediatric Annals, 15 (9): 583-594. September 1986.

This article discusses the distribution, prevalence, vectors, and pathophysiology of Lyme disease and its clinical manifestations and medical treatment. Lyme disease has been reported in 24 states on the U.S. mainland, and in 19 countries on three continents since its recognition of signs and symptoms and history of exposure in an endemic areas. (33 references)

Finkel, M.F.

"Lyme Disease and its Neurologic Complications" (review).
Archive of Neurology, 45 (1): 99-104. January 1988.

This review discusses the life cycle of the vector that transmits Lyme disease and the neurologic syndromes associated with the disease. Lyme disease is recognized as a cause of illness involving multiple organ systems. The transmission of the *Borrelia burgdorferi* spirochete depends on a complicated vector life cycle, involving multiple mam-

malian and avian hosts. Although the illness is reported worldwide, variable clinical presentations on different continents raise questions about disease mechanisms. Multiple neurologic syndromes can occur alone or in combination, producing peripheral neuropathies, radiculopathies, encephalitides, meningitides, and pain syndromes. These may be noted with dermatological, rheumatological, and cardiologic syndromes. This review also discusses several pathophysiologic mechanisms and antibiotic therapy for different clinical presentations. (107 references)

Finkel, M.F.

"Lyme Disease: Its Neurological Manifestations and Its Presentation in Wisconsin."

Wisconsin Medical Journal, 85 (7): 9-13. July 1986.

This article reviews the cause, states, and treatment of Lyme disease. By the late 1970's this disease was recognized as a systemic disorder with dermatologic, neurologic, rheumatologic, and cardiac components. The three stages of Lyme disease include ECM and associated symptoms, neurologic and cardiac abnormalities, and rheumatologic symptoms. After the discovery of the causing spirochete, it was found that the Lyme disease of the United States is the same as the European disease Bannwarth syndrome. The recommended treatments for early Lyme disease are tetracycline, phenoxymethyl, penicillin, and erythromycin. The author suggests the following illnesses be considered in the differential diagnosis of Lyme disease: serum sickness, systemic lupus erythematosus, rickettsial infections, periarthritis nodosa, Vogt-Koyanagi-Harada disease, hepatitis B, central nervous system syphilis, mycoplasma, Behcet's syndrome, multiple sclerosis, infectious mononucleosis, viral encephalitis, leptospirosis, and Mollaret's meningitis. (32 references)

Grodzicki, R.L. and Steere, A.C.

"Comparison of Immunoblotting and Indirect Enzyme-Linked Immunosorbent Assay Using Different Antigen Preparations for Diagnosing Early Lyme Disease."

Journal of Infectious Diseases, 157 (4): 790-797. April 1988.

This article compares immunoblotting and indirect enzyme-linked immunosorbent assay (ELISA) using different antigen preparations to test for antibody to *Borrelia burgdorferi* in patients with early Lyme disease. With immunoblotting, 16 (53%) of 30 patients had positive tests in acute phase sera and 25 (83%) had them in convalescent-phase sera. Among 64 controls, false-positive results were obtained in only three individuals with syphilis and one hospitalized patient with renal allograft rejection. Among the patients with Lyme disease, both IgM and IgG antibodies most commonly bound to the 41-kilodalton (kDa) flagellar antigen, but many patients had binding to other components, particularly those of 25, 55, 58, or 66 kDa, and the order of their appearance was variable. Compared with indirect ELISA (using sonicated whole spirochetes or a flagellin-enriched fraction as the antigen preparation), more patients with Lyme disease had positive tests by immunoblotting, and fewer control subjects had false-positive results. The results indicate that immunoblotting is superior to indirect ELISA for diagnosing early Lyme disease. (18 references)

Halperin, J.J.; Little, B.W.; Coyle, P.K.; and Dattwyler, R.J.

"Lyme Disease: Cause of a Treatable Peripheral Neuropathy."

Neurology, 37 (11): 1700-1706. November 1987.

This article discusses peripheral nerve dysfunction, which was demonstrated in 36% of patients with late Lyme disease. Of 36 patients evaluated, 14 had prominent limb paresthesia. Thirteen of these had neurophysiologic evidence of peripheral neuropathy; neurologic examinations were normal in most. Repeat testing following treatment documented rapid improvement in 11 of 12. The authors conclude that this neuropathy, which is quite different from the infrequent peripheral nerve syndromes previously described in this illness, is commonly present in late Lyme disease. This neuropathy presents with intermittent paresthesia without significant deficits on clinical examination and is reversible with appropriate antibiotic treatment. Neurophysiologic testing provides a useful diagnostic tool and an important measure of response to treatment. (41 references)

Lawson, J.P.; Steere, A.C.

"Lyme Arthritis: Radiologic Findings."

Radiology, 154 (1): 37-43. January 1985.

Lyme disease is a newly recognized, multisystem disorder that may be associated with chronic arthritis. Of 25 patients with severe arthritic manifestations, the most frequent radiographic finding was knee joint effusion. Intra-articular edema was often accompanied by a continuum of soft-tissue changes involving the infrapatellar fat pad, periarticular soft tissues, and the entheses, which were sometimes thickened, calcified, or ossified. Later in the illness, the joints of some patients showed typical changes of an inflammatory arthritis, including juxta-articular osteoporosis, cartilage loss, and cortical or marginal bone erosions. Less commonly, other patients demonstrated changes more characteristic of degenerative arthritis, including cartilage loss, subarticular sclerosis, and osteophytosis. Joint involvement of Lyme disease has similarities to juvenile arthritis and Reiter's syndrome, but can usually be distinguished clinically and serologically from these entities. (37 references)

Luft, B.J., Volkmann, D.J.; Halperin, J.J.; Dattwyler, R.J.

"New Chemotherapeutic Approaches in the Treatment of Lyme Borreliosis."

Annals of the New York Academy of Science, 539: 352-361. August 26, 1988.

It was demonstrated that while *B. burgdorferi* may be sensitive to relatively small concentrations of penicillin and ceftriaxone, the organism is killed slowly. This implies that, as in syphilis, prolonged blood levels of these drugs may be necessary in order to ensure cure. In contrast, the activity of tetracycline is more rapid in its action but is more dependent on drug concentration achieved. Unfortunately, the MIC and MBC for some strains are at or above the peak level achieved under optimal condition. Increasing the concentrations of penicillin or ceftriaxone above the MIC for the organism has little effect on the rate of killing. In contrast, the killing by tetracycline can be augmented by increasing concentrations of the drug. Ceftriaxone is more active than penicillin, as measured by MIC, against the five strains of *B. burgdorferi* tested. Ceftriaxone was efficacious in the treatment of Lyme borreliosis, which was recalcitrant to penicillin therapy. In a randomized trial comparing ceftriaxone to high-dose penicillin therapy, ceftriaxone was significantly more efficacious than penicillin in the treatment of the late complications of Lyme borreliosis. (17 references)

Markowitz, L.E. et al

"Lyme Disease During Pregnancy."

Journal of the American Medical Association, 255 (24): 3394-3396. June 27, 1986.

Because the etiologic agent of Lyme disease is a spirochete, there has been concern about the effect of Lyme disease on pregnancy outcome. The authors reviewed cases of Lyme disease in pregnant women who were identified before knowledge of the pregnancy outcomes. Nineteen cases were identified with onset between 1976 and 1984. Eight of the women were affected during the first trimester, seven during the second trimester, and two during the third trimester; in two, the trimester of onset was unknown. Thirteen received appropriate antibiotic therapy for Lyme disease. Of the 19 pregnancies, five had adverse outcomes, including syndactyly, cortical blindness, intrauterine fetal death, prematurity, and rash in the newborn. Adverse outcomes occurred in cases with infection during each of the trimesters. Although *B. burgdorferi* could not be implicated directly in any of the adverse outcomes, the frequency of such outcomes warrants further surveillance and studies of pregnant women with Lyme disease. (28 references)

Metz, L.E.; Wobig, G.H.; Duffy, J.; and Katzman, J.A.

"Ticks, Spirochetes, and New Diagnostic Tests for Lyme Disease."

Mayo Clinic Proceedings, 60 (6): 402-406. June 1985.

The cause of Lyme disease is the spirochete, *Borrelia burgdorferi*, isolated from *Ixodes dammini*, *Ixodes pacificus*, and *Amblyomma americanum*. The first stage of Lyme disease is characterized by the presence of erythema chronicum migrans (ECM) and nonspecific influenza-like symptoms. Stage two is characterized by neurologic or cardiac abnormalities and occurs in 15% and 8% of cases, respectively. Stage three is characterized by arthritis and occurs in about 60% of cases. No deaths from Lyme disease have been reported and the spirochete is effectively treated with antibiotics. Complications can be avoided or substantially ameliorated by prompt diagnosis and treatment in the early stages. (15 references)

Pachner, A.R. and Steere, A.C.

"The Triad of Neurological Manifestations of Lyme Disease: Meningitis, Cranial Neuritis, and Radiculoneuritis." *Neurology*, 35 (1): 47-53. January 1985.

This article reports on a study of 38 patients with Lyme meningitis, a newly recognized spirochetal infection. The patients characteristically had intermittent attacks of severe headache, mild meningismus, and predominantly lymphocytic pleocytosis. In addition to meningitis, 11 patients experienced subtle encephalitic signs, 19 had cranial neuritis, most commonly unilateral or bilateral facial palsy, and 12 developed peripheral radiculoneuritis, plexitis, or mononeuritis multiplex. Without antibiotic therapy, the duration of neurologic involvement was three to 18 months. Although sometimes incomplete, the triad of neurologic manifestations of Lyme disease-meningitis, cranial neuritis, and radiculoneuritis—presents a unique clinical picture. (41 references)

Reik, L., Jr.; Burgdorfer, W.; and Donaldson, J.O.

"Neurologic Abnormalities in Lyme Disease Without Erythema Chronicum Migrans." *American Journal of Medicine*, 81 (1): 73-78. July 1986.

This article describes the clinical features in eight patients with neurologic abnormalities typical of Lyme disease and elevated titers of antibody to the spirochete, *Borrelia burgdorferi*, its causative agent. None of the patients had the diagnostic skin lesion, erythema chronicum migrans. Lyme arthritis, the other clinical marker for the disease, developed subsequently in only three. The neurologic abnormalities included aseptic meningitis, encephalitis, cranial neuritis, motor and sensory radiculitis, and myelitis in various combinations. The occurrence of severe encephalitis resulting in dementia in two of these patients and irreversible myelopathy in one enlarges the known spectrum of neurologic abnormalities due to infection with *B. burgdorferi*. Lyme disease can present with neurologic abnormalities without diagnostic extraneural features, can be suspected on clinical and epidemiologic grounds, and can be diagnosed serologically. (20 references)

Schned, E.S. and Williams, D.N.

"Lyme Disease: The Tick Bite, the Rash, and the Sequelae." *Postgraduate Medicine*, 77 (5): 303-308, 310. April 1985.

Originally diagnosed in 1975, the transmitting agent in Lyme disease, a spirochete, was not identified until 1983. The disease is found primarily in the northeastern coast, upper Midwest, and Pacific Northwest of the United States from May to October when ticks are most prevalent. Lyme disease is characterized by a distinctive skin rash called erythema chronicum migrans and by cardiac and neurologic abnormalities in about 10% of patients. Laboratory tests will reveal an elevated ESR but other tests are normal or negative. Immune complexes, cryoglobulins, T-cell lymphopenia, and elevated titers of IgM and IgG antibodies are found in many patients. Differential diagnosis is based on the pattern of arthritis, lack of laboratory abnormalities, and contact with an endemic area. Early treatment with antibiotics reduces the likelihood of major sequelae. Should these occur, penicillin is used for neurologic abnormalities, analgesics or anti-inflammatory agents for arthritis, and aspirin and prednisone for cardiac manifestations. (25 references)

Shrestha, M.; Grodzicki, R.L.; and Steere, A.C.

"Diagnosing Early Lyme Disease." *American Journal of Medicine*, 78 (2): 235-240. February 1985.

This article discusses a prospective study of the diagnostic value of clinical, culture, and serologic findings in 41 patients with early Lyme disease. Fifteen patients had erythema chronicum migrans alone, and 26 had clinical evidence of disseminated infection, most commonly affecting the brain or meninges, other skin sites, lymph nodes, or joints. Of 40 blood cultures, only one, from a patient with disseminated infection, yielded spirochetes. One of 10 patients tested with localized infection had an elevated IgM response to the Lyme spirochete (200 units or greater). Of the 22 patients tested with disseminated disease, 10 initially had elevated levels of specific IgM or IgG, and 12 had such responses by convalescence. Because of the low yield of cultures and the delay in the specific antibody response, recognition of the clinical picture remains very important in diagnosing early Lyme disease. (24 references)

Skoldenberg, B.; et al.

"Treatment of Lyme Borreliosis with Emphasis on Neurological Disease." *Annals of the New York Academy of Sciences*, 539: 317-323. August 26, 1988.

The authors studied 113 patients with neurological Lyme borreliosis and meningitis who were treated with intravenous high-dose antibiotics (penicillin G, 12 g, mostly for 14 days in 47 patients; penicillin G, 9 g mostly for 10 days in 58 patients). Seventy percent of the patients had peripheral nerve symptoms and 13% had central nervous symptoms. Almost half of the patients were treated more than four weeks after the onset of symptoms and 15% of the patients had persisting or progressive symptoms between 4 and 11 months. There seemed to be clinical benefits as well as a decreased of spinal fluid pleocytosis and spinal proteins. No significant symptoms of Herxheimer reaction was demonstrated. (15 references)

Steere, A.C.; Schoen, R.T.; and Taylor, E.

"The Clinical Evolution of Lyme Arthritis."

Annals of Internal Medicine, 107 (5): 725-731. November 1987.

Fifty-five patients who did not receive antibiotic therapy for erythema chronicum migrans were followed longitudinally for a mean duration of six years. Of the 55 patients, 11 (20%) had no subsequent manifestations of Lyme disease. From one day to eight weeks after disease onset, 10 of the patients (18%) began to have brief episodes of joint, periarticular, or musculoskeletal pain for as long as six years, but they never developed objective joint abnormalities. From four days to two years after disease onset, 28 (51%) had one episode or began to have intermittent attacks of frank arthritis, primarily in large joints; a few had polyarticular movement. The total number of these patients who continued to have recurrences decreased by 10% to 20% each year. The remaining six patients (11%) developed chronic synovitis later in the illness; of these, two (4%) had erosions, and one (2%), permanent joint disability. The spectrum of Lyme arthritis ranges from subjective joint pain, to intermittent attacks of arthritis, to chronic erosive disease. (24 references)

Steere, A.C., et al.

"The Early Clinical Manifestations of Lyme Disease."

Annals of Internal Medicine, 99 (7): 76-82. July 1983.

Lyme disease, caused by a tick-transmitted spirochete, typically begins with a unique skin lesion, erythema chronicum migrans. Of 314 patients with this skin lesion, almost half developed multiple annular secondary lesions; some patients had evanescent red blotches or circles, malar or utricular rash, conjunctivitis, periorbital edema, or diffuse erythema. Skin manifestations were often accompanied by malaise and fatigue, headache, fever and chills, generalized achiness, and regional lymphadenopathy. In addition, patients sometimes had evidence of meningeal irritation, mild encephalopathy, migratory musculoskeletal pain, hepatitis, generalized lymphadenopathy and splenomegaly, sore throat, nonproductive cough, or testicular swelling. These signs and symptoms were typically intermittent and changing during a period of several weeks. The most common nonspecific laboratory abnormalities were a high sedimentation rate, an elevated serum IgM level, or an increased aspartate transaminase level. Early Lyme disease can be diagnosed by its dermatologic manifestations, rapidly changing system involvement, and if necessary, by serologic testing. (32 references)

Steere, A.C. et al

"Successful Parenteral Penicillin Therapy of Established Lyme Arthritis."

New England Journal of Medicine, 312 (14): 869-874. April 4, 1985.

A double-blind placebo-controlled trial was carried out from 1980 to 1982, in which 20 patients with established Lyme arthritis were assigned treatment with 2.4 million units of intramuscular benzathine penicillin weekly for three weeks (total, 7.2 million units) and 20 patients received saline. Seven of the 20 penicillin-treated patients (35%) had complete resolution of arthritis soon after the injections and have remained well during a mean follow-up period of 33 months. In contrast, all 20 patients given placebo continued to have attacks of arthritis ($p < .02$). In 1983, of 20 patients treated with intravenous penicillin G, 20 million units a day for 10 days, 11 (55%) had complete resolution of arthritis and have remained well since. As compared with nonresponders, penicillin-responsive patients in both studies were more likely to have previously received antibiotics for erythema chronicum migrans ($p < .02$) and less likely to have been given intraarticular corticosteroids during or at the conclusion of parenteral therapy ($p < .01$). The Lyme spirochete was not cultured from synovium or joint fluid. The authors conclude that established Lyme arthritis can often be treated successfully with parenteral penicillin. However, neither of the regimens tested is uniformly effective, and further experience will be needed to determine the optimal course of therapy. (24 references)

Antibiotic Streamlining—Scope, Format, and Benefits

PAMELA HENDERSON, PHARM.D., AND HELEN M. CROWE, M.D.

BECAUSE anti-infective drugs constitute a major portion of the pharmacy budget at most hospitals, monitoring their usage is a logical starting point for cost containment strategies.

Antibiotic "streamlining" is the name given at Hartford Hospital to the process of converting patients from complicated, often expensive antibiotic therapy to equally efficacious, simpler, and less expensive regimens. An antibiotic streamlining pilot program was instituted at Hartford Hospital in 1986. Results of this program were so promising — a projected annual cost savings of nearly \$108,000 and an 83% compliance rate by clinicians with program recommendations¹ — that the program became staffed by full-time personnel in 1988.

The streamlining team at Hartford Hospital consists of a physician from the Infectious Disease Division and a Doctor of Pharmacy from the Pharmacy Department who review the records of the patients in several categories for possible inclusion in the streamlining program: 1) those receiving two or more intravenous (IV) antibiotics; 2) those receiving any IV antibiotics for more than three days; and 3) those receiving certain broad-spectrum antibiotics which must be ordered on a special "Antibiotic Order Form." When the streamlining team feels a change in therapy is necessary, they communicate their views to the clinician both orally and on a printed form left in the patient's chart. The form does not remain part of the permanent medical record and the recommendations are not mandatory for the clinician.

As noted in Table 1, there are typically three stages in the use of antibiotics in hospitalized patients.² When a

patient suspected of having an infection is admitted, he or she is often seriously ill and empiric antimicrobial therapy is broad enough to cover multiple potential pathogens. During this early stage of hospitalization, our antibiotic review consists primarily of eliminating antibiotic combinations with redundant bacterial coverage (eg, nafcillin plus cefazolin for suspected *S. aureus* infection) and correcting dosing errors. After three days, the patient is usually more stable, and the results of microbiological tests have become available. At this point, patients on multiple antimicrobials can often be given a single drug based on culture results.

After five to seven days of antimicrobial therapy, many patients can be changed from intravenous to oral therapy. Drugs well-absorbed by the oral route, such as ciprofloxacin, trimethoprim-sulfamethoxazole, and metronidazole, have proved especially useful. For example, an inpatient with a mixed infection originating in a pyogenic liver abscess was treated with ticarcillin/clavulanic acid and gentamicin for two weeks with substantial improvement. Traditional therapy would have been six weeks of intravenous antimicrobials. However, because of the patient's rapid improvement and his desire to return home, he was given oral ciprofloxacin and metronidazole in the hospital; he continued to improve and was discharged to complete an additional month of oral therapy at home. His liver abscess was shown to resolve completely on serial computed tomographic scans.

This patient's case illustrated many of the benefits—real and potential—of antibiotic streamlining. Nearly \$2,500 was saved in acquisition costs of drugs alone, and his intravenous catheter was removed, decreasing the risk of phlebitis or infection.

This patient was among the first 15 enrolled in the streamlining program during August 1988. This pool of 15 was selected from a group of 97 patients receiving multiple antibiotic therapy. Twenty patients were excluded because they were being seen by infectious disease consultants; therapy was considered appropriate in the remaining 62 patients, many of whom were later "streamlined" by their own physicians when culture results

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Editors: Moses Sing Sum Chow, Pharm. D., and Robert A. Quercia, M.S., R.Ph.

Table 1
Three Typical States of Antibiotic Therapy in
Hospital-Associated Infections

Stage	Patient's Condition	Treatment
I (days 0-3)	Clinically unstable; uncertainty as to causative organism(s) and often even site of infection	Combination therapy or monotherapy with an expanded-spectrum beta-lactam drug
II (days 4-6)	Begins to stabilize; causative organism(s) usually identified and clinical data often indicate site of infection	Simplification usually possible: Combination therapy changed to monotherapy or monotherapy with a more narrow-spectrum drug or one with preferred pharmacokinetics; if patient can take an oral drug, therapy is possible with oral agents with excellent bioavailability, tissue penetration, and intense microbiologic activity (eg, trimethoprim-sulfamethoxazole, metronidazole, fluorinated quinolones)
III (days 7 and beyond)	Clinically stable; patient now in hospital for completion of treatment of infection or other medical problems, or both	Oral therapy is often possible, or parenteral therapy with drugs having long serum half-lives

became available. Of those 15 patients in whom recommendations were made, the suggested changes were

made in 86%. Eight of the patients had initially received three intravenous drugs, while seven had received two intravenous drugs. All patients survived to discharge; there were two complications: 1) a drug rash in a patient given trimethoprim-sulfamethoxazole, and 2) a prolonged fever, discovered to be secondary to extrinsic obstruction of a ureter (which was not characterized further). The average drug acquisition and administration cost savings was \$345 per patient or \$5,153 per month. In addition to these savings, the program provided quality assurance data to the appropriate hospital committees and a mechanism for improving therapeutic use of antibiotics in the hospital.

The program has enrolled more than 120 patients in the following several months and we are continuing to evaluate the effect of antibiotic streamlining on the duration of hospital stay and the course of the patient's infection. The support of the medical staff throughout this program has been excellent.

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1. Quintiliani R, Cooper BW, Briceland LL, Nightingale CH: Economic impact of streamlining antibiotic administration. *Am J Med* 1987;82(Suppl 4A):391-4.
2. Briceland LL, Nightingale CH, Quintiliani R, Cooper BW, Smith KS: Antibiotic streamlining from combination therapy to monotherapy utilizing an interdisciplinary approach. *Arch Intern Med* 1986;148:2019-22.

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Gianetti v Norwalk Hospital: Connecticut Supreme Court Rules on Hospital and Medical Staff Member Contractual Relationship and Judicial Review of Medical Staff Termination Decisions

STEPHEN E. RONAI, ESQ. AND PHYLLIS E. HYMAN, ESQ.

THE long-awaited decision in *Gianetti v Norwalk Hospital*, 211 Conn. 51 (1989), was released by the Connecticut Supreme Court on 25 April 1989. The Court held that the administrative decision of a hospital governing board to refuse to reappoint the plaintiff physician to its medical staff was subject to judicial review by the Superior Court. The Court further held that a contractual relationship was formed when the defendant Norwalk Hospital agreed to provide the use of its facilities and resources to the physician in the grant of staff privileges and when the physician, in a complementary promise, agreed to abide by and conform his conduct to the standards established in the medical staff bylaws.

The Court's Distinction Between Current Medical Staff Members and New Applicants

Although the Court's holdings with respect to judicial review and the existence of a contractual relationship incorporating bylaws may be viewed as disturbing to hospitals, the Court declined to extend contractual rights and judicial review to applicants to the hospital's medical staff who are denied initial appointment. The Court held in another portion of its decision that the adoption by a hospital of medical staff bylaws is an activity mandated by the Public Health Code. See Regulations of Conn. State Agencies, section 19-13-D3 (b) (1) (A). The hospital's performance of its preexisting legal duty to adopt medical staff bylaws did not, according to the Court, constitute valid consideration to create an enforceable contract for a physician applying for staff privileges for the first time.

The Demise of the Rule of Non-Review

The Court's holding impliedly overruled the thirty-year precedent in *Edson v Griffin Hospital*, 21 Conn. Supp. 55 (1958). *Edson* established a rule of "non-review"

of hospital medical staff decisions on the rationale that Connecticut hospitals were private corporations and that review of medical staff privilege decisions would interfere with the "internal management" of the affairs of a private corporation. Thus, Dr. Edson, who had his surgical privileges limited by the Board of Directors of the Griffin Hospital, could not, in 1958, obtain a judicial examination of either the validity of the procedure used by the Board of Trustees in limiting his privileges or the validity of the evidence supporting the reasons for that medical staff privilege limitation. Without recourse to remedies in the Connecticut courts, dissatisfied physicians after the *Edson* decision were left to seek relief through federal or state antitrust remedies or due process claims.

The efficacy of federal antitrust remedies for physicians in such situations has been sharply limited by the enactment of the Health Care Quality Improvement Act of 1986, discussed briefly *infra*. In addition, physician claims based on alleged violations of federal constitutional due process have not been viable in the Second Circuit (which includes Connecticut) since that Court's decision in *Schlein v Milford Hospital, Inc.*, 561 F.2d 427 (2d Cir. 1977). In *Schlein*, the Court held that action by a private, nonprofit community hospital did not constitute action by the state for purposes of due process claims, despite state licensure, tax exemptions, and substantial funding. Therefore, until the *Gianetti* decision, most avenues to the courts for physicians whose staff privileges had been revoked or limited were effectively barred.

However, the rules of the game are now changed with respect to the availability of judicial relief in the Connecticut courts based on a breach of contract claim. In addition to the federal and state antitrust remedies, the *Gianetti* decision incorporates the hospital's medical staff bylaws in the contract between the hospital and the physician. The bylaws become an "integral part of the contractual relationship." Inherent in the contractual relationship is the right of the staff physician to protect

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his rights and vindicate them through remedies for breach of contract in the Connecticut courts.

The Scope of Review: The Extent of the Connecticut Court's Future Involvement Was not Clarified

Although the Court created a new contractual right for staff physicians, it was less clear in defining the scope or standard of review to be employed by the Superior Court in determining whether a staff physician denied reappointment would be entitled to relief. The Court did imply that judicial review must at least determine whether the terms of the contract — the procedural requirements of the hospital's medical staff bylaws — have been followed by the hospital. Thus, the inquiry in future lawsuits would require the Court to determine whether a physician received adequate notice, a fair hearing, the right to face his accusers, to examine documents, and all of the other procedural steps contained in the bylaws.

The opinion does not suggest that the hospital's substantive reasons for the termination, suspension or limitation (which relate to the physician's competence, ability to work with others, and other bylaw admission standards) will be closely examined beyond the record provided by the hospital. However, the Court did refer to a standard of review used by the New Jersey Courts in their judicial examination of medical staff privilege decisions. New Jersey has adopted the "public trust" doctrine to characterize the duties of the trustees of New Jersey private nonprofit hospitals.¹ Because New Jersey Courts characterize hospital trustees and officials as fiduciaries, their examination of staff privilege decisions requires close scrutiny not only of the procedure used by the hospital but also of the hospital's criteria and the evidence in the record to support the reasons for the termination. The determination of the scope of the Connecticut standard for reviewing medical staff decisions will be left to development in future litigation.

Careful Adherence to Medical Staff Bylaw Procedures Will Blunt the Effect of the Gianetti Doctrine

Although *Gianetti* creates a new Connecticut judicial remedy for disgruntled medical staff members, it should not require hospital administrators, medical staff credentials committees, and hospital trustees to change their behavior. If a hospital medical staff acts in the interest of sustaining quality patient care, then it should have no difficulty preparing an adequate evidentiary record of a physician's alleged inadequacies. Furthermore, it should have no difficulty following the procedural steps which are spelled out clearly in the hospital's medical staff bylaws. The *Gianetti* contractual remedy should not result in the imposition of any liability on a hospital that has created a careful documentary record of medical staff peer review and has adhered to the procedural steps in the medical staff bylaws and in developing that record.

The force of the *Gianetti* decision is further undercut by the Health Care Quality Improvement Act of 1986, 42 U.S.C.A. section 11101 *et seq.* ("The Act"). The Act provides statutory protection for conformity to medical staff bylaws for it immunizes the hospital and all persons involved in the peer review process from federal antitrust liability as long as the due process protections mandated by the Act are contained in the hospital's bylaws and followed by the hospital in the medical staff credentialing process. Thus, the Act and the *Gianetti* decision provide a double incentive for hospitals to ensure adequate procedural protections in their medical staff bylaws and to adhere strictly to those procedures.

REFERENCES

1. See *Greisman v Newcomb Hosp.*, 40 N.J. 389, 192 A.2d 817 (1963). See also *Berman v Valley Hosp.*, 103 N.J. 100, 510 A.2d 673 (1986) (hospital staff admission policy invalid because hospital considered a quasi-public entity and policy not related to genuine and legitimate health care objective); *Desai v St. Barnabas Medical Center*, 103 N.J. 79, 510 A.2d 662 (1986) (particular closed-staff policy chosen by hospital invalid because it did not serve a public health objective).

HIV Epidemic and AIDS: Trends in Knowledge — United States, 1987 and 1988

CENTERS FOR DISEASE CONTROL, ATLANTA

EDUCATION and information can play an important role in preventing human immunodeficiency virus (HIV) transmission by reducing high-risk behaviors and encouraging safe practices. To collect information for developing and targeting new education programs, the National Health Interview Survey (NHIS) began in August 1987 to include specific questions to assess the public's knowledge about the transmission, prevention, and consequences of HIV infection; attitudes toward persons already infected; and awareness and utilization of the HIV-antibody test.

NHIS is a continuous, cross-sectional household interview conducted by CDC's National Center for Health Statistics (NCHS). Each week, a national probability sample of the civilian, noninstitutionalized population is interviewed by Bureau of the Census personnel to obtain information on health, demographic, and other characteristics of each household member. Supplemental information is collected for all or a sample of household members. The 1987 and 1988 NHIS acquired immunodeficiency syndrome (AIDS) knowledge and attitudes questionnaires were administered to one randomly chosen adult ≥ 18 years of age in each household. The estimates in this report are based on the approximately 3500 interviews completed each month.

The first NHIS AIDS Knowledge and Attitudes Survey was implemented from August to December 1987, and provisional survey results were published monthly.¹⁻⁵ From January to April 1988, the NHIS AIDS questionnaire was revised to include questions about the brochure, "Understanding AIDS," which was mailed to every U.S. household in May and June. The revised AIDS Knowledge and Attitudes Survey was implemented in May 1988, and provisional results are being published periodically.⁶⁻⁹

The current questionnaire contains items on self-assessed knowledge about AIDS, HIV transmission, perceived effectiveness of various preventive measures,

experience with blood donation and testing, and self-assessed likelihood of being seropositive. In the survey, the term "AIDS virus" was used in place of HIV, and that wording has been maintained in this report. All estimates in this report are provisional. Unless otherwise indicated, all changes and differences cited in the text are statistically significant. ($p < 0.05$).

Baseline Findings

In August 1987, the proportions of U.S. adults who responded that they knew "a lot" and "some" about AIDS were 20% and 40%, respectively (Table 1). Sixty-seven percent of adults had discussed AIDS with a friend or relative; of those adults who had children 10-17 years of age, 60% had discussed AIDS with their children; 36% reported that their children had received AIDS education in school (Table 1).

Most adults answered that they had "no" chance (60%) or a "low" chance (30%) of acquiring the AIDS virus (Table 1). Although 70% of adults had heard of the blood test to detect the presence of HIV antibody, only 15% had had their blood tested, including 7% who reported having had their blood tested and 8% who reported having donated blood since 1985, when routine testing of donation began.

Thirty-four percent of adults considered use of a condom as "very effective" in preventing HIV infection, and 84% answered that having a monogamous relationship with an uninfected partner is a "very effective" preventive measure (Table 1). Two percent of adults responded that use of a diaphragm or spermicidal jelly, foam, or cream are "very effective" preventive techniques.

Most adults knew that AIDS is a fatal disease and that no cure for AIDS exists (89% and 83%, respectively) (Figure 1). Seventy-five percent answered that it was "definitely true" that the AIDS virus can be transmitted during sexual intercourse; 69%, that it was "definitely true" that a pregnant woman can pass the AIDS virus to her baby; 91%, that it was "very likely" that a person would acquire the AIDS virus from sharing needles for drug use with a person who has AIDS (not shown in the

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figure). The proportions of adults who responded that it was either “probably true” or “somewhat likely” that HIV could be transmitted in these three ways were 18%, 22%, and 5%, respectively.

Sixty-five percent of the adults responded that the following were “definitely false”: a vaccine is available to the public that protects against the AIDS virus; AIDS is especially common in older persons; and it is possible to tell by looking at someone if he or she has the AIDS virus.

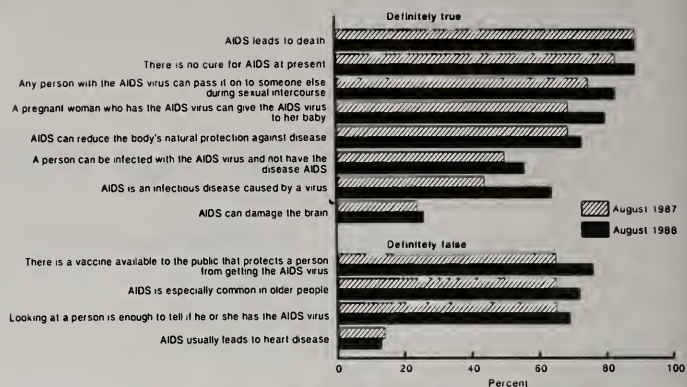
Seventy-four percent of respondents answered that it is “very unlikely” or “definitely not possible” to transmit the AIDS virus by living near a hospital or home for AIDS patients; 58%, by attending school with a child who has the AIDS virus; 53%, by working near someone with the AIDS virus; 40%, by using public toilets; and 27%, by sharing eating utensils with someone who has the AIDS virus (Figure 2).

TABLE 1. Measures of knowledge, attitudes, and behaviors among adults surveyed about HIV and AIDS — United States, August 1987 and August 1988

Measure of knowledge	August 1987 (%)	August 1988 (%)
Self-perceived level of knowledge about AIDS:		
A lot	20	22
Some	40	44
A little	30	26
None	10	7
Percentage of adults who:		
Have ever heard of a blood test that can detect the AIDS virus infection	70	75
Have ever had their blood tested for the AIDS virus infection	15	17
Expect to have a blood test for the AIDS virus infection in the next 12 months	3	4
Have ever discussed AIDS with a friend or relative	67	65
Have ever discussed AIDS with their children aged 10-17	60	60
Report that their children aged 10-17 have received AIDS education in school	36	59
Self-perceived risk of getting the AIDS virus:		
High	1	0
Medium	4	2
Low	30	20
None	60	75
Don't know	5	3
Perceived effectiveness of selected methods of preventing AIDS virus transmission through sexual activity:		
Using a diaphragm—		
Very effective	2	2
Somewhat effective	11	12
Not at all effective	56	57
Don't know	31	29
Using a condom—		
Very effective	34	29
Somewhat effective	48	54
Not at all effective	6	4
Don't know	12	12
Using a spermicidal jelly, foam, or cream—		
Very effective	2	1
Somewhat effective	13	14
Not at all effective	54	55
Don't know	31	30
Two people who do not have the AIDS virus having sex only with each other—		
Very effective	84	84
Somewhat effective	9	7
Not at all effective	1	2
Don't know	6	8

Changes Between August 1987 and August 1988

Between August 1987 and August 1988, both objective and self-assessed measures of knowledge increased (Figure 1). Over this period, the proportion of adults who answered that it was “definitely true” that AIDS is an infectious disease caused by a virus increased from 44% to 64%. The proportion responding that it was “definitely true” that a pregnant woman can transmit HIV to her baby increased from 69% to 80%. The proportion



SOURCE: National Center for Health Statistics, Division of Health Interview Statistics, National Health Interview Survey.

Figure 1
Provisional estimates of percentage of adults responding correctly to selected AIDS knowledge items — United States, August 1987 and August 1988.

answering that it was “definitely false” that a vaccine exists that protects against HIV infection increased from 65% to 76%. The proportion of adults responding that they knew “a lot” about AIDS increased from 20% to 22%; adults answering that they knew “some” about AIDS increased from 40% to 44% (Table 1).

A substantial increase occurred in the proportion of adults who answered that the AIDS virus could *not* be transmitted through casual contact with infected person (Figure 2). In August 1987, 35% of adults responded it was “very unlikely” that person could become infected with the AIDS virus by working near someone with and 18% responded that it was “impossible.” In August 1988, these proportions had increased to 40% and 27%, respectively.

The perceived effectiveness of condoms (“very effective” or “somewhat effective”) in preventing HIV transmission remained essentially the same (Table 1), as did attitudes about the other forms of contraception and the perceived “effectiveness” of a mutually monogamous relationship with an uninfected partner.

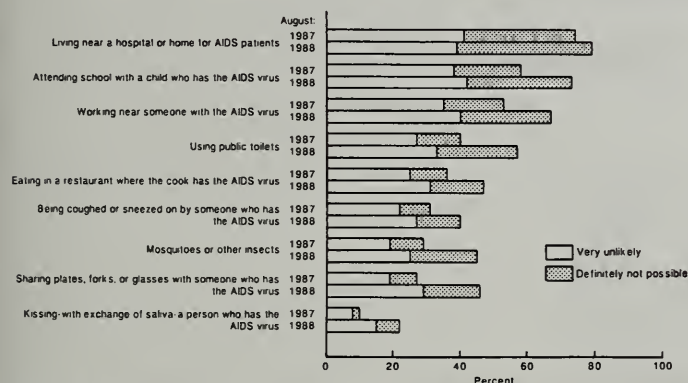
The proportion of adults who had heard of the blood test for early diagnosis increased from 70% to 75%. In August 1988, 17% of adults had been tested, including 9% who reported having had their blood tested and 8% who reported having donated blood since 1985.

The proportion of adults reporting their chances of becoming infected with HIV as “high” or “medium” showed limited change (1% to < 1% [nonsignificant], 4%-2%, respectively), but a large proportion shifted from the low-risk to no-risk category, the latter increasing from 60% to 75%.

Three percent of adults reported that they belonged to one or more of the groups associated with increased risk for HIV transmission. Among these persons, perceived risk for HIV transmission varied: 5% reported that their chances of already having been or of becoming infected with HIV were “high,” 7% reported a “medium” chance, and 42% reported a “low” chance of infection.

The proportion of adults who reported discussing AIDS with their children aged 10-17 years remained at 60%; in contrast, the proportion who reported that their children had received AIDS education in school increased from 36% to 59%. Little change occurred in the proportion who reported having discussed AIDS with friends or relatives.

Reported by: Div of Health Interview Statistics, National Center for Health Statistics; National AIDS Information and Education Program, Office of the Deputy Director (HIV), CDC.



SOURCE: National Center for Health Statistics, Division of Health Interview Statistics, National Health Interview Survey.

Figure 2
Provisional estimates of percentage of adults who think it very unlikely or definitely not possible to transmit the AIDS virus in selected ways—United States, August 1987 and August 1988.

Editorial Note: In comparing August 1987 to August 1988, the most substantial increase in knowledge was related to transmission of HIV. The increases in the percentages of adults who considered it “very unlikely” or “definitely not possible” to transmit HIV through various forms of casual contact represent important gains in knowledge.

The overall gain in levels of knowledge about HIV and AIDS coincided with the national multimedia public awareness campaign. Analysis of the NHIS data is under way to assess the impact of one element of this campaign, the mailing of the brochure entitled “Understanding AIDS” to every U.S. household during May and June 1988. Evaluation of this and other public education efforts will help guide future campaigns so that progress can continue.

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The Oath, the Art, the Caring

Three recent experiences inaugurated this personal reappraisal and resultant editorial.

First, I had the pleasure to review Dr. Julius Landwirth's article for *Connecticut Medicine* which I commend to all readers' consideration (1989;53:47-9). A patient failed to sue her primary physician for mal-results post-operatively but instead directed suit against the third-party payer that had recommended truncating her necessary hospital stay. The court, on appeal, turned the case around to heap culpability on her physician. It was he as "captain of the ship" who was ultimately responsible for writing the discharge order. His compliance with the third party negated the rapport he had carefully built and the care he had rendered to *his* patient. We are admonished once again to curb costs and to order tests fiscally carefully, but always mindful that we as physicians will be blamed ultimately for any mal-results, interpreted or actual.

Second, I attended a recent symposium at a prestigious university, updating the problem of back pain, compensation claims, and the burgeoning marketplace where claims of cure from acupuncture to Zen are rampant. The sponsors clearly appreciated the complex interplay of many professionals by virtue of their invitations to various experts and the list of topics they had selected for presentation. However, individual speakers were far from complimentary and often bordered on the inflammatory when directing barbs at lawyers, insurance carriers, chiropractors, massage parlors, and the like, for creating and promulgating out-of-work behaviors. The bashing continued for two days even while the same speakers reiterated the lack of quality controlled, randomized, prospective, double-blind, and statistically precise, cost-comparative, primary-investigator unbiased studies in the conventional medical and surgical literature that would solidly establish value and reproducibility in nearly all current treatment protocols for back pain sufferers. Finally in a practice management seminar, I was treated to a view that physicians need to be ever mindful of the many facets of day-to-day operation of the Business of Medicine. Highlights included 13 ways employees could embezzle funds, ways insurance carriers could modify (lower) your profile to cut your gross receipts, methods patients have to circumvent the payment of your bill, and finally ways unsuccessful employees or fired former employees can sue you and succeed in winning big pay-offs guaranteed. Update courses supposed to highlight novel technologies and standards of care in the forum of continuing medical

education are now heavily weighted to include investment portfolio advice, management subsections, third-party payment techniques, and office design and selection. Nursing advertisements on a recent New York radio airway offered quotes by these professionals to the effect that they would never allow their sons or daughters to enter their field. Many physicians at our own institution recommended M.B.A's and technical schools rather than M.D.'s for their own children.

I asked myself what was happening, and a light came on. Some children recite the Pledge of Allegiance each morning to enhance their sense of loyalty and faith in priorities and principles. In the 10 years since my graduation from medical school, one of the most uplifting days of my life and one closely wed to the WOW-day of actual acceptance to medical school, I had not heard, read, or even considered the Oath I took with 229 fellow graduates. I searched in texts and journals; I plowed through drawers and stacks, old boxes, and diplomas.

The Hippocratic Oath was not just easily accessible, not part of the daily battle armor. Having found it, however, I reproduce it here for your consideration and dissection. Remember, as you read, the bright-eyed, promise filled, hopeful faces of new physicians who spoke its words once with you. Reflect on your vision and wonder then — as compared to now.

The Oath of Hippocrates

"I swear by Apollo the physician, and Aesculapius, and Health and All-heal, and all the gods and goddesses, that, according to my ability and judgment, I will keep this Oath and this stipulation — to reckon him who taught me this Art equally dear to me as my parents, to share my substance with him, and relieve his necessities if required; to look upon his offspring in the same footing as my own brothers, and to teach them this art, if they shall wish to learn it, without fee or stipulation; and that by precept, lecture, and every other mode of instruction, I will impart a knowledge of Art to my own sons, and those of my teachers, and to disciples bound by stipulation and oath according to the law of medicine, but to none others. I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous. I will give no deadly medicine to any one if asked, nor suggest any such counsel; and in like manner I will not give to a woman a pessary to produce abortion. With purity and with holiness I will pass my life and practice my Art. I will not cut persons laboring under the stone, but will leave this to be done by men who are practitioners of this work. Into whatever houses I enter, I will go into them for the benefit of the sick, and will abstain from every voluntary act of mischief and corruption; and, further from the seduction of females or males, of freemen

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and slaves. Whatever, in connection with my professional practice or not in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret. While I continue to keep this Oath unviolated, may it be granted to me to enjoy life and the practice of the art, respected by all men, in all times! But should I trespass and violate this Oath, may the reverse be my lot!"

Fellow practitioners of our art, let us honestly search our hearts for direction. Let us focus on the care we ought to give, unblinded by deflections of the Business of Medicine. Let us bend to our science and its method to assure quality instead of paying lip service to it by committees formed to regulate the crossing of t's and the dotting of i's. Let us bash not the practitioners of other arts and sciences whose methods may not be conventional but who care for the patients they serve. Their success is often measured not by cure but by attention to the needs of suffering humanity — hands on, touch, care, attention, and interest. The wonders of medical practice are very high tech — CT, MRI, genetic engineering, and the pharmacological intervention into every bodily cascade and enzyme flux. There is a lot of no touch and depersonalizing interventions in what we do. But holism, high touch, personal contact, and absolutely constant attention to the humanistic details cannot be ignored or obviated. The hospital halls and office waiting rooms are bastions to be preserved. Podiatrists, chiropractors, Ph.D.'s, drug reps, nurses, therapists, physicians, and surgeons better all get back to basics. We are all caring professionals by Oath and by unwritten laws dedicated to providing the best, most honorable, most up-to-date, most caring service to those in need, in suffering, in birth, in life, and in death. Though the legal profession and the insurance industry, the government bureaucracies and the quality assurance, risk management, and peer review and assessment-of-stay panels may stalk our every move, the Oath remains our rock and our fortress. "I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous." Our honorable charge, earned by personal efforts, long hours of sacrifice and study, and financial turmoil to achieve the schooling and training and to survive it all, unmarred by anger and upset, with spirit and stamina, is to love our patients, bills paid or not, to intercede for them against their disease and dis-ease, to comfort them in their sorrow, to be part of the intricacies and secrets and innermost thoughts, memories, and dreams of their lives. We need no peer review — we have our lofty Oath and our precious motives.

We may be bashed for our successes or perceived wealth but few will deny us the midnight hours in the pit with the drunks, the substance abusers, the vomit, the blood, and the feces and filth. We need to get our heads and hearts back up high where we deserve to be, earning respect and not sniveling and wallowing in issues regarding that "they" are doing to us. We must get up, get

organized effectively, get vocal, get fortified, realizing that the best defense is a good offense, and that offense does not necessarily require us to be offensive.

Earl McBride, M.D., F.A.C.S., summarized the Art this way:

What is the secret of the Art
That marks the goodness of the doctor's name?
What is the silent force and part
It plays in his success and fame?
Is it knowledge, wit, and genius
Or his boldness, bluff and pride?
It is being shy and unpretentious
Resigned, complacent or self-satisfied?
Search his record great or small,
There is a quiet factor from within
That all inspiring spirit doctors call
The ancient art of medicine.
Tho' valued great, this simple art
Is not for purchase price or sale.
It comes through grace of heart,
The sunshine of the doctor's daily trail.
Try define it as you may,
This modest buoyant force you'll find,
Springs from the soul and so we say
'Tis but the art of being kind.¹

It might be too idealistic to expect that the patients who sue, and the lawyers who stalk, and the insurance carriers who cut, would publish their own codes of right conduct and standards of morality. But we, as those who offer care, need to be as perfect as human beings can be, attentive and honorable as we ought, and dedicated and energized by our work and by the lives we touch. Our battle is with cancer, not with our fellow care providers; we should not be fighting for marketing turf or for a bigger cut of the pie. Quality work and attention to detail are rewarded by enhanced referrals. Our struggle is with the AIDS virus, not with a few virulent lawyers and inflammatory patients. Our energies should be directed to more thorough investigation and research and to continuing medical education, not diverted to financial and malpractice seminars which would erode the time needed to enhance our science.

This is America, land of opportunity, hope of millions. Medical professions have historically been honored, revered, attractive vocations for the best and the brightest. The Oath, carefully studied and dutifully implemented will protect our goals from erosion and from the dust of the marketplace. The humanism of dedicated professionals will keep us all where we deserve to be — respected, forthright, honest, and unsullied practitioners of our Oath and Art. If any of this makes any sense or enhances insight, it might even put the fun back into getting up in the morning.

Frank W. Maletz, M.D.

New London, CT

REFERENCE

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Mandatory HIV Testing in Hospitals



Seldom has a resolution referred by the Council to the House of Delegates for action resulted in such an outpouring of letters to the Society. The debate at the House of Delegates May 10, 1989, confirmed the depth of interest and emotion in this issue.

This issue: Resolved, that routine and mandatory HIV testing of all patients on admission to an acute care hospital be adopted, as policy, by the CSMS House of Delegates; and be it further

Resolved, that this resolution be transmitted to the American Medical Association with the request that routine and mandatory HIV testing of all patients on admission to acute care hospitals be adopted as an AMA policy...

The practicing physicians who formulated this resolution listed their concerns in the preamble to the resolution printed in the Handbook for the meeting. Several spoke to them on the floor of the House. The extreme standards of confidentiality and informed consent have compromised public health monitoring and prevented more effective infection control. Prohibiting routine testing and confidential disclosure to health care workers violates their own right to know of their exposure to risk. Health care professionals are obligated ethically to make disclosure of risk to their colleagues and patients if they are HIV positive but are not accorded similar rights when exposed to HIV positive patients. The effectiveness of universal precautions is not yet proven. The cost of routine testing added to that of universal precautions must be weighed against the value of preventing occupational exposure and infection. Immediate treatment with prophylactic AZT of health care workers exposed to the AIDS virus makes prior knowledge of the unsuspected HIV positive patient increasingly important.

Other physicians spoke against the resolution including members of the Public Health Committee, Department of Health Services, and the Infection Disease Section. A letter from Frederick G. Adams, D.D.S., M.P.H., Commissioner of Health, challenged the validity of the reasons listed above. His letter with several others had been distributed to the delegates with the Handbook prior to the meeting. Many physicians spoke. Concern was expressed about mandatory testing of low risk patients and diversion of scarce funds to this purpose with damage to other aspects of the Public Health Program. A physician, with the patient's consent, can perform this test at any time. The finding of a negative HIV test on hospital admission will not screen out an early case.

After more discussion and debate than this short article reflects, the resolution was defeated.

During the debate the official policy of the American Medical Association was not considered. Perhaps, it would be pertinent to do so now.

An official policy statement was issued by the AMA late 1988 regarding testing: "Testing for the AIDS virus should be readily available to all who want to be tested. As a matter of medical judgment, physicians should encourage voluntary HIV testing for individuals whose history or clinical status warrants testing. Before testing, the patient should be counseled on effective behavior to avoid risk of AIDS for themselves and others. Patients found to be seropositive should be counseled on responsible behavior to prevent the spread of the disease, strategies for health protection with a compromised immune system, and the necessity of alerting sexual contacts within the last 5-10 years regarding their possible infection by the AIDS virus. Certain high risk groups should be regularly tested, with a right to informed consent and to refuse the test: patients at sexually transmitted disease clinics and drug clinics; first trimester pregnant women in high risk AIDS areas; and those seeking family planning from high incident areas or who engaged in high risk behavior. Testing for the AIDS virus should be mandatory for donors of blood and blood fractions, organs and other tissues intended for transplantation; for donors of semen or ova; for immigrants to the United States; for inmates in federal and state prisons; and for military personnel."

Roger S. Beck, M.D.
President

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The Character of Our Mortality

ROBERT U. MASSEY, M.D.

A discovery young physicians often make soon after they leave the peculiar world of the teaching hospital is that many of their new patients, in contrast to those they recall from residency days, have no need to consult them at all. Their diseases are either self-limited or their complaints appear to have no objective reality. No tests are positive, and there are no distinctive physical findings. That their diseases are "functional" seems clear from their complaints: they are tired, insecure, nervous, and depressed, or, at least, anxious and worried.

Trying to explain how anxiety, anger, or self-doubt can produce fatigue, giddiness, headache, backache, abdominal pain, chest pain, loss of appetite, and impotence without implying that these symptoms are all in the patient's head gives rise to intense and even disabling anxiety in the young physician. "Doctor, are you trying to tell me I'm imagining all this?" When there are two angry patients, one of whom has already been waiting almost an hour and the other even longer, and the phone has rung three times, and it is past 5:30, getting involved in a credible explanation of the mind-body relationship with convincing examples, including some drawn for emphasis from the physician's own life, may be more than is manageable.

So we learn to use names, names as proxies for explanation, and then in time we come to accept them ourselves; if we can name something we must understand it. Chronic irritable colon, functional bowel distress, fibrositis, palindromic rheumatism were names in vogue at mid-century. Before that there had been colitis, visceroprosis, neurasthenia, and general diathesis, and long before that, and perhaps the most honest of all, simply melancholy. Harmless names, with one or two notable exceptions, and not without practical value.

It was easier before diseases came to be located quite precisely in organs, and then in tissues and cells. Understanding disease as an imbalance of humors had made more sense because when one got sick one felt bad all over. No laboratory tests were needed; that the depressed or tired patient's constitution was out of balance was abundantly evident. Cellular pathology changed all of

that until the hormones were discovered; it was then a small step back from hormones to humors, and desiccated thyroid, gr. ii, became in time one of the panaceas; fatigue and a BMR less than minus 10 cinched the diagnosis. If the patient were female and over 45, parenteral estrogen could be added, along with thiamine and elixir of luminal for nerves. Alternative diagnoses were vitamin B₁₂ deficiency and in some cases reactive hypoglycemia.

There were also the chronic infections, analogous to tuberculosis, which certainly produced fatigue and depression. You remember Walpole's nuciform sac in Shaw's, *The Doctor's Dilemma*, "...full of decaying matter—undigested food and waste products—rank ptomaines." The vermiform appendix, sometimes the colon, the gallbladder, the tonsils, the sinuses, and the teeth were all possible, indeed likely, sources of mischief. These foci of infection giving rise to diseases, of otherwise unknown etiology, were cess-pools generating fatigue and lowness of spirits. And there were elusive infectious diseases like undulant fever, and who knows what others, that defied diagnosis.

Now we have discovered the chronic fatigue syndrome, the postviral fatigue syndrome, persistent Epstein-Barr virus infection, and Lyme disease. The diagnoses are objectively real: some patients are chronically fatigued, viral illnesses are often followed by long periods of lassitude, EBV antiviral antibodies can be identified in some, and Lyme disease is epidemic in Connecticut. The mistake may come in thinking that we have explained the patient's disease when we find traces of a virus, or elicit a history of erythema chronicum migrans, or confidently unmask all the faces of depression, in short, give it a name. The truth, as we all surely know, lies deeper than our nosologies can take us, and Robert Burton was closer to it when he wrote:

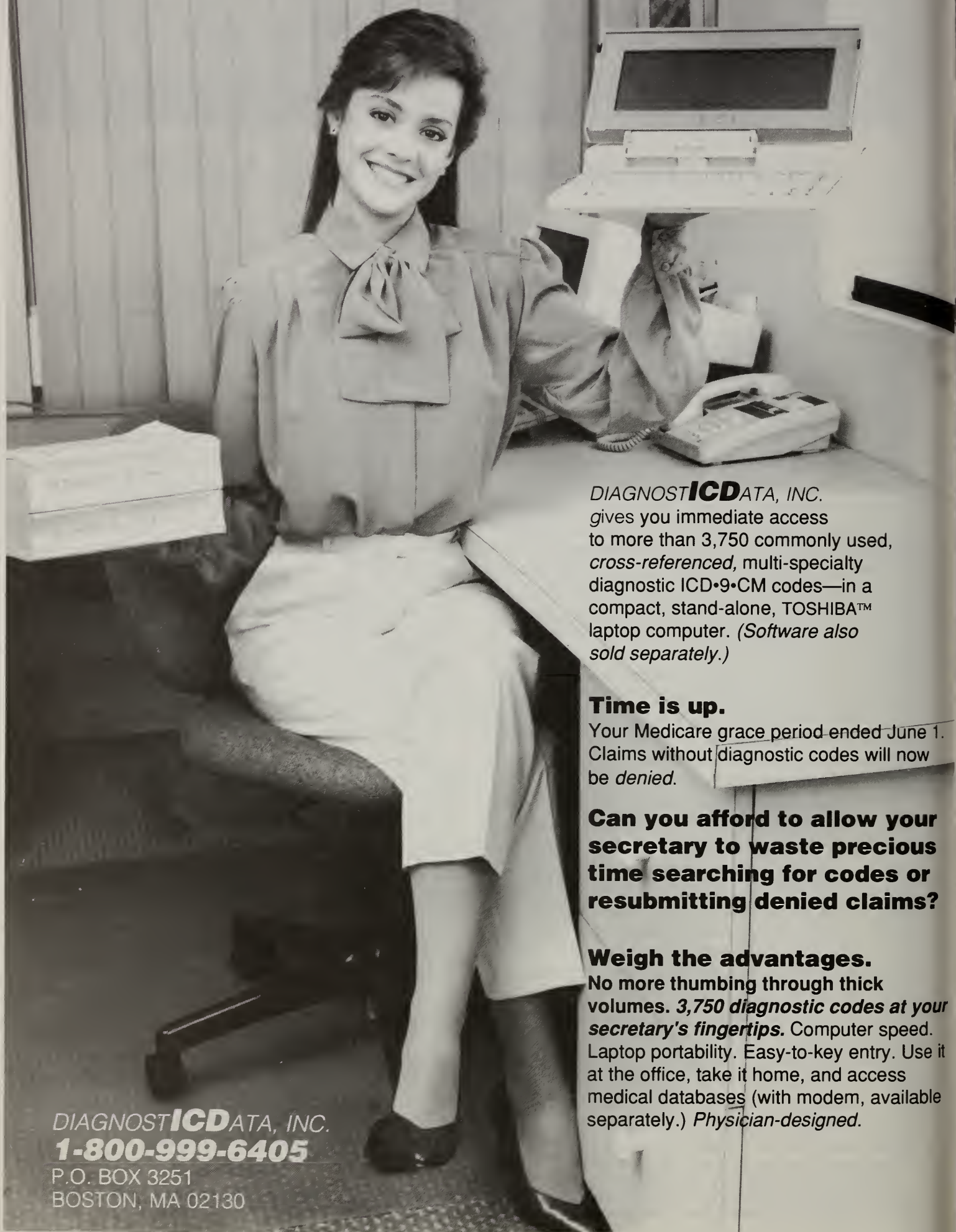
"And from these melancholy dispositions, no man living is free, no Stoic, none so wise, none so happy, none so patient, so godly, so generous, so divine, that can vindicate himself; so well composed, but more or less, some time or other, he feels the smart of it. Melancholy in this sense is the character of mortality."¹

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1. Burton, R: *The Anatomy of Melancholy*, Pt. I, Sec. I, Mem. I, Subs. V., 1621.

ROBERT U. MASSEY, M.D., Professor, Division of Humanistic Studies in Medicine, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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50 Years Ago
From the *Journal of the Connecticut State Medical Society*
July 1939

Address by His Excellency, Raymond Baldwin,
Governor of the State of Connecticut*

Medicine rapidly is becoming — if it has not already become — the last rallying point of this thing that we call “Our Civilization.” Once we said “Art,” “Religion,” “Music,” “Literature” — yes, even “Science.” *They* knew no race, no politics, no nationalism, we used to say. The artist, the minister of God, the musician, the great writers and scientists — *they* were for the world. Today, we see great books being burned, their authors exiled, because of racial hatreds. We see Art banished, great works of music forbidden. We see Science shackled, perverted, the greatest scientists driven out of their homelands. We see Religion, on the one hand trampled upon, persecuted, beaten down, or on the other hand used merely as a propaganda agency for some monstrous State. Only in Medicine does the world, apparently, still ride upon an even keel.

Very recently, there was held here in this country a meeting, as I understand it, of medical men, military medical men, from all of the countries of the world. Perhaps some of you gentlemen here tonight attended it. There were English and German, French, Japanese, Russian, Spanish and Italian, Scandinavian and South American — all were there — doctors and surgeons, dental men and specialists of every description. And the man who told me about the meeting said: “You know, Governor, it was the most amazing thing! No other such meeting could be held, would be possible, in the world today! There they all were, meeting together to exchange information, to help one another, to give one another the best of each other’s experience and discoveries, freely, cooperatively, hopefully, *not* on the basis of race or nationality, but simply as *doctors*, medical men, whose duty it was to all humanity!” In what other field of human endeavor today would you discover that to be

possible?

You medical men live today in a sick world. Our civilization is stricken unto death, afflicted by tumors and cancerous growths, its bloodstream poisoned, its nervous system disarranged to a point where, perhaps, in some instances, a psychiatrist rather than a medical man would better be called in. Here in our country, probably because we are big and husky, we have succeeded (to date, at least) in throwing off infections from abroad. Oh, we are not immune, we have broken out in a rash here and there, and here or there we have come down with a fever of long or short duration. But we have not — not yet — come down, seriously, with any of these foreign ailments. Truth is, we have enough ailments of our own, right here, to contend with. If I were a doctor called in to attend Uncle Sam in this illness of his I think I should diagnose his case as fifty per cent — at least fifty per cent! — hypochondria. And the other fifty percent I think should blame on the “doctors,” the “doctors” who have been attending him and prescribing for him. There’s such a thing, is there not, as *too many* blood transfusions? — *too many* injections? As a matter of fact, even, I’m afraid the “doctor’s” bed-side manner, in attending the patient, isn’t all that it should be. The important thing, I’m told, is to instill confidence, confidence in the “doctor’s” ability, and *self*confidence in the patient himself.

We’ve got a sick man, here, an accident case. He was in a pretty bad crash. He broke a leg, *both* legs, and an arm or two, and a half dozen ribs, and suffered internal injuries besides, to say nothing of a nasty bump on the head. But the worst of it was shock. He was in considerable pain, too. A sedative was in order (I have no doubt of it); but you can’t go on administering sedatives indefinitely. Besides, it’s my private conviction that the broken

*Abstract of address delivered at 147th Annual Meeting, New Haven, May 25-26, 1939.

bones are healed, long since healed.

What do you do with a patient recovering from a broken leg? Do you permit him to go on lying in bed with his leg in a cast *indefinitely*? Or do you say to him: "You must begin to *use* that leg as soon as you are able, else the muscles will become atrophied." I do not know how you doctors would do it, but I do know we must get our patient back onto his feet... Before much more serious complications set in than have yet developed. We can not ethically, much longer encourage a neurotic that looks hopefully to continued medication, artificial stimulents, indefinitely prolonged hospitalization. There are so many *other* things waiting to be done!

Government's job is to assist, collaborate, if you will, but *never* to take over. This I believe, that no person, man, woman, or child, in this land of ours should, through no fault of his own, because of unemployment, or inability to pay, — no man, woman or child should have to go without adequate medical care — *ever*!

Medicine itself, I think, has recognized its high duty to humanity in this respect. I do not refer to our hundreds of privately endowed hospitals, clinics and similar institutions. Their services to the unfortunate are too well known, too widely recognized, to require repetition. But I can not forego this opportunity to pay my respects to you medical men, medical men and women, too to *you*, individually. I know from countless reports how hard the sledding has been, these past years, for medical men everywhere, the city specialists and the country general practitioner. I know you people, some of you, have had a hard time making ends meet. And yet I venture to say not one of you, not one of you here today, not one of you throughout the country, not one of you but has, upon occasion after occasion, given unselfishly and unsparingly of your time, your skill, your knowledge, time after time, without thought of compensation. To little individual families in your home communities or neighborhoods, to individuals — just plain people — *good* people! The good people of this State and Nation owe you, our doctors, an undying debt of gratitude, not for some great institutional, machine-like functioning (although for these, our great clinics and hospitals, we are grateful, too), but for your *individual*, countless many kindnesses.

You have been truly America's Good Samaritans.

AROUND THE STATE

Robert M. Jeresaty, M.D., of West Hartford, Director of the Section of Cardiology at Saint Francis Hospital and Medical Center, was honored during the opening ceremonies of the hospital's 25th Annual Cardiovascular Symposium, the longest-running annual cardiovascular symposium in the United States.

Eric H. Gluck, M.D., of Glastonbury, is the developer and tester of an experimental lung ventilating machine that was among the top six patented inventions selected to compete for the "National Inventor of the Year" for 1988.

E. Marvin Henken, M.D., of West Hartford, has been elected by the Connecticut State Radiological Society as one of the two Connecticut members of the Council to the American College of Radiology. Dr. Henken, a fellow of the college, was elected to a two-year term.

Jay D. Smith, M.D., of West Hartford, received the *Volunteer of the Year Award* from the Combined Health Appeal of America. He is a board member of the Combined Health Appeal and chairman of the CHA-CT Wellness Task Force.

"Withholding and Withdrawing Artificial Nutrition and Hydration" is the title of a conference to be held in the Keller Auditorium of the University of Connecticut Health Center on Saturday, 23 September 1989.

This is the first in a series of continuing education programs exploring current legal, ethical, and medical controversies in health care. The program will be of interest to physicians, judges, attorneys, hospital administrators, nursing home administrators, nurses, allied health professionals, social workers, and members of the general public interested in legal and ethical issues at the end of life.

For more information, call Cecile J. Volpi, Director, Office of Continuing Education, 679-3340.

The Department of Pediatrics, Bridgeport Hospital, will offer The Maxwell Bogin Symposium, "Preventive Aspects of Pediatric Care," at the Bridgeport Hilton, Bridgeport, CT, 4 October 1989. 5 CME credits. For further information call Thomas L. Kennedy, M.D., Chairman, Department of Pediatrics, (203) 384-3712.

"Current Concepts in Neuromuscular Diseases," a one day symposium sponsored by the Connecticut Neurological Society/University of Connecticut School of Medicine, Department of Neurology, to be held in Farmington on Friday, 17 November 1989. Information: Susan Crawford, University of Connecticut School of Medicine, Department of Neurology.

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

LEARNING THE ART

To the Editor: I write to congratulate you on your essay, "Reflections on Medicine: Too Much Science?" in the February issue of *Connecticut Medicine*.

Your last paragraph has particular impact in referring to what so many have called the "art" of medicine. I feel that with the recent debate on residency time commitments, that too many administrators and physicians are missing some of the subtle points of what the long hours of residency training do to physicians. These individuals concern themselves with the narrow focus of continuity of care and the value of long hours in the learning experience and miss the edges of that focused picture, ie, the time for these physicians in training to be able to go to the theatre, to be able to go and see a film, to be able to bounce off and reflect on life's experiences through other outlets that will give greater dimension to the practice of medicine. The corollary to that as well is to decrease the inbred resentment and narrow-mindedness that comes from working long hours in the sleep-deprived state.

Giving young physicians the opportunity to round out their education by giving them time to do so will allow "those with eyes to see" to realize that goal.

Unfortunately, with the way our medical education system has evolved, after medical school there are rare opportunities for residents to learn the art of medicine by example. Certainly this is not done in the clinics of our universities and very little in the private offices of the affiliated hospitals. But by giving these young, bright, enthusiastic minds the chance to teach themselves, I think a great many of them will learn by experience.

Derrik F. Woodbury, M.D.

Bloomfield, CT

Dr. Woodbury wrote the following article for *The New Physician* in March 1980 when he was a resident in orthopedic surgery at the Mary Hitchcock Memorial Hospital in Hanover, New Hampshire. It is reprinted with permission.

WHAT'S WRONG WITH GENERAL SURGERY TRAINING

Rounds at 6:30 a.m. Frequent, exhausting call for several years. Long working days. Despite all this, for many, the detrimental aspects of a general surgical resi-

dency are more than balanced by the satisfaction of being an internist who can operate, by the challenge of surgical physiology, and by the fulfillment gained from performing skilled procedures competently.

However, when medical students make their career decisions, they are seldom based on an impartial, logical analysis of pros and cons, benefits and drawbacks, likes and dislikes. They are usually rooted in a firm foundation of ignorance and intuition, twisted and tainted by subjective impressions from brief experiences. Students must bridge an ineffable void. They do this through a process of identification with their surgical attendings. When they look at those attending, they ask, "Is this the type of person I want to be in 20 years?"

Too often, the answer is negative. Not because all surgical attendings are ogres, but because of an antiquated surgical education process, mired in tradition and intimately intertwined with personalities.

Medical students traditionally look forward to their general surgical clerkship with about as much anticipation as an organic chemistry final. They are not afraid of the long hours of hard work. On the contrary, they are almost uniformly idealistic, enthusiastic, and willing to learn and to apply their knowledge practically. But their innocence is quickly blunted as they are expected to hold retractors for hours in positions that cramp their bodies and prevent them from observing the surgical procedure. They feel self-conscious in the foreign environment of the operating room. The circulator instills harshly the fear of contamination. The scrub nurse paralyzes them with a gruff manner and harshly tells them to stay away from her back table. The anesthetist abruptly tells them not to lean on the patient. The attending comes in late. Harried and hassled, he (seldom she) repeatedly repositions the students' retractors, implying that each slip is a deliberate ploy to sabotage the operation. The students cannot see what they are exposing, or not exposing, but to complain would be to lose one's place. Other than the patient, they are the only other people paying to be in the operating theatre. Under the hot lights, oppressive gowns, and intimidating circumstances, their fingers fumble for the suture scissors as the attending yells, "I said CUT! GOD-DAMNIT . . . TOO LONG!"

How can a medical student possibly stay interested in a five-hour aorto-bifemoral graft placement by merely hanging on the end of a retractor? Any intelligent mind would become bored; anybody would become hungry and fatigued. And any person would associate those unpleasant feelings with surgery. The attending surgeon does not comprehend. His mind and fingers are active every second. The time passes quickly for him. The surgical resident must keep his/her place. He is not the "captain of the ship." He is trying to keep mistakes to a minimum in his own realm. Then the moment arrives: the skin is about to be closed. The attending surgeon has left the room. The atmosphere has changed. Now, will a couple of skin sutures make up for the previous five

hours?

Never.

Suddenly everyone in the operating room is conscious that his or her back hurts. It is 12:35 and the cafeteria closes at 1:00 p.m. The student's brief shining moment is abruptly snatched away. The scrub nurse yells at him not to use so much suture material. His fingers seem dissociated from his mind, and he can't help but notice that the resident is placing seven sutures to his every one—and his look better. The student's knots unravel as he ties them. The anesthesiologist snickers and offers a multitude of suggestions, each seeming to conflict with its predecessor. After an eternity of frustration, the resident reaches the student's suture line. The scrub nurse elbows the student out of the way. The bandage is placed. The ordeal is over.

Or has it just begun? For there are numerous bloods to be drawn. Lab values must be researched. X-rays pulled for rounds. There are two admissions, and the second case begins in 20 minutes.

The students look forward to seeing a cholecystectomy. They have heard much about gallbladder disease. Unfortunately, from their position in the left upper quadrant of the operating field, they can't see the gallbladder. There is a different attending surgeon, and he pays them more attention. No, they have not read up on the anatomy, the students answer in subdued tones and begin to feel like persons of poor moral fiber. They stammer through the anatomy of the retroperitoneum, but the attending laughs. "Don't they teach anatomy in medical school anymore?" he bellows. The students want to crawl in the wound and hide. When it comes time to close the skin, it is 3:00 p.m. The nurses want to go home. The resident was on call the evening before and wants to make rounds early. The situation has not improved.

In such a setting the medical students are vulnerable. They are susceptible to kindness. That kindness has to come from the top. A friendly scrub nurse can ease the pain, but the mood in the operating room is set by the attending surgeon. Are the rigors of a general surgical residency such that only calloused, inflexible people emerge? Would it slow down a procedure so terribly if a student did one suture of each anastomosis? Very few operations would be significantly halted, the students would retain their interest, and the principles and sequence of events would be recalled in greater detail.

The apprenticeship of surgery is intimidating and every human being wants to feel important. If attending surgeons paused to reflect on the human qualities possessed by students and residents, and treated them with the sensitivity and respect they accord their private patients, they would enhance their own presence as well as set precedents for future generations. Their example would create role models capable of inspiring talented young physicians. They would allow surgery to be judged by its merits instead of its distractions.

CANADA'S MEDICAL CARE SYSTEM

To the Editor: This letter is in response to Dr. Robert Massey's editorial, "Reflections on Medicine, A Simpler, Kinder System." I would like to take exception to some of his comments relating to the Canadian-style health care system. While he does point out that the Canadian model is far from perfect, he implies that it is superior to that in the United States.

It is true that Canada spends less on health care, but it is also true that Canadians receive less care. Rationing of care has become a real fact of life in Canada. For example, the entire country has only 12 hospitals with magnetic resonance imaging equipment (with no other MRI facilities outside of hospitals). In Vancouver, patients must wait one to three months for psychiatric, neurosurgical, or routine orthopedic consultation and six months for cataract surgery. Patients in Quebec must wait six months for angiograms and eight months for coronary artery bypass surgery.¹

The specter of higher taxes, rationing of care, lack of new technology, and cutbacks in research and education loom very large in national systems including that of our neighbor to the north. We all agree that our health care system must be strengthened in order to provide access for all, but to dismantle an entire system which provides the most sophisticated level of care in the world would be a grave mistake. Access for all can be accomplished without adopting a model which would end up being a disservice to the American people — our patients.

Joseph C. Czarsty, M.D.

Oakville, CT

Chairman of the Council, CSMS

REFERENCES

1. *American Medical News*. 32 (14), April 14, 1989.

From the Executive Director's Office

COUNCIL MEETING Thursday, June 8, 1989 Organizational Meeting

The organizational meeting of the Council for 1989-90 was called to order by the President, Roger Beck, M.D. Following brief remarks and introduction of all Council members, elections of a Chairman and Vice-Chairman of the Council for 1989-90 were held. It was VOTED to elect Joseph Czarsty, M.D., Oakville, Chairman, and Joseph S. Sadowski, M.D., Hartford, Vice-Chairman.

Attendance

Present in addition to the Chairman, Dr. Joseph C. Czarsty were Drs. Ahamed, Beck, Bobruff, Catrini, Freedman, Fox, Kamens, Kaufmann, Keating, Jr., Lesnik, McDonnell, Meridy, Orphanos, Petrie, Petro, Reylet, Jr., Robbins, Sosa, Wetstone, Zanker, and Zeppieri.

Also present: Mr. Norbeck, Mr. Brunell, Mr. Sullivan, Mr. Staples, Ms. Connelly, Mr. Tomat (FCMA), Mr. Coffey (HCMA), Ms. Harney (NHCMA), Dr. Massey, and Mrs. Reed (President, Auxiliary).

Absent were: Drs. Blum, Bonner, Chmielewski, Dardick, Eslami, Hollister, Jr., Parikh, Redmond, Rose, Sadowski, Schwartz, Welch, and Zlotzky.

Change in Time of Council Meetings

It was agreed to start future Council meetings at 2:30 P.M. instead of 1:30 P.M. with the Fiscal Subcommittee meeting starting at 1:00 P.M. This change would be on a trial basis, and it was emphasized that all meetings would begin promptly at 2:30 P.M.

Approval of Minutes

It was VOTED to approve the minutes of the March 29, 1989 with one amendment which was to change CMMI to CMIC in the Report on CMMI and CMIC activities on Page 4, to read "future of CMIC."

Reports on Related Organizations

CPRO: Edward Kamens, M.D. reported that CPRO is attempting to educate physicians on the mandated "point system" for peer review quality care issues and will be using brochures, informational material and speakers in this effort. There appears to be great concern about this program and Dr. Kamens stated he will be available to speak on this subject before any hospital staff or groups. It was reported that CPRO will be designated to do peer review for the Medicaid program.

Commissioner of Health Services vs Harold Kadish

During the discussion on peer review, the subject of the case of the Commissioner of Health Services vs Harold Kadish was raised and the effect it would have on the peer review function. In accordance with the Council directive on March 29, a letter was sent to all CSMS

members that there exists increased risk to them for all peer review activities they may undertake. Tim Norbeck reported that Wiggin and Dana was in the process of preparing an update on the implications of the case. Robert Brunell indicated that CSMS has requested a meeting with the legal staff of the State Department of Health Services to develop a protocol relating to the Department's use of their subpoena power. CSMS hopes to obtain the right to prevail upon people to voluntarily provide necessary information before the State uses its subpoena power. CSMS will probably seek the necessary confidentiality statutes in the next session of the legislature.

CMMI-CMIC: James Orphanos, M.D. submitted a written report on CMMI and CMIC activities which included information that CMIC is preparing the upcoming rate structure and that the legislature has increased the surcharge on the corporate tax from 15% to 20!, again increasing the pressure on rates. Last fall's indications of a softening market was reinforced and it was reported that St. Paul's is reentering the market nationally and other competition may be following. He announced that Drs. Mehdi Eslami and Daniel Doctor and Mr. Tim Norbeck were elected unanimously as Chairman, Vice-Chairman and Secretary.

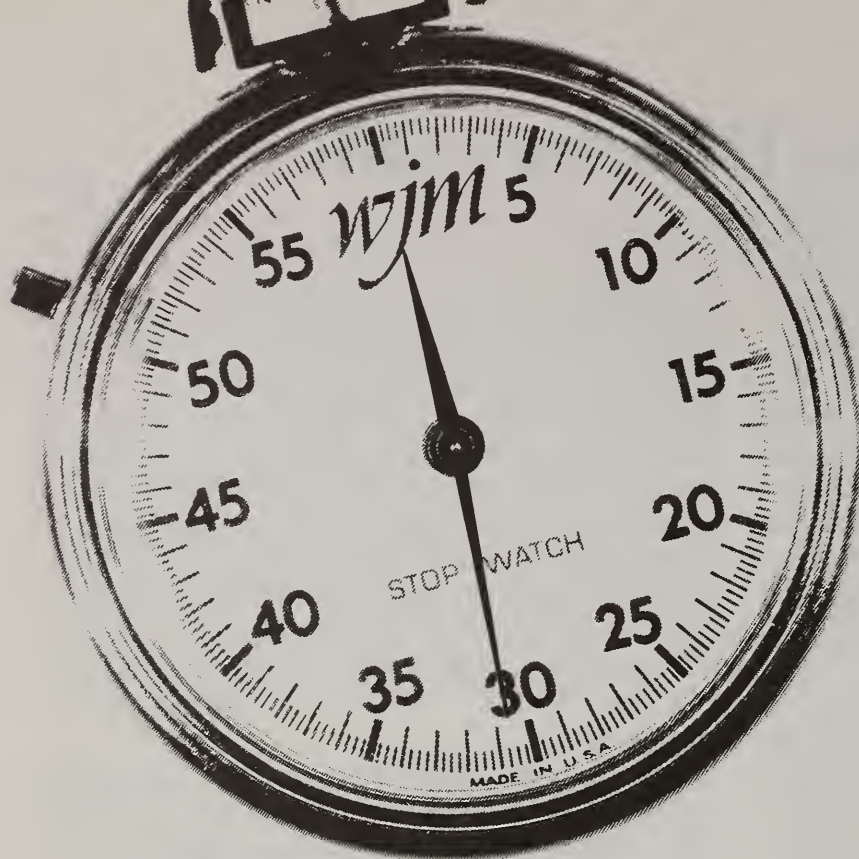
Dr. Sultan Ahamed commended Dr. Orphanos for all his efforts as president of CMMI for the past three years and stated that his input into CMMI and CMIC will continue to be valuable in the future. It was requested that this commendation be put on the record as an expression of the Council.

M.D. Health Plan: Dr. Vincent Catrini, Vice-Chairman of the Board of Directors of M.D. Health Plan, reported that as of June 1989 enrollment had increased to approximately 22,500, 5,000 of whom are in the MedChoice program. This far exceeded their anticipated goal. It appears that MDHP will achieve a financial break-even point in the very near future, and he stated that the support of CSMS has made this possible.

Report of the President

AMPAC: Dr. Beck presented a letter from AMPAC concerning AMPAC membership. According to the letter, Connecticut is ranked twenty-eighth in AMPAC membership, with 12.6% of physicians contributing. He encouraged members to join.

Council of New England State Medical Societies: He reported that the theme of the meeting was the need for unity in the ranks of medicine and that to eliminate the infighting, there is a need to identify common ground. In an effort to unify the profession within the state, Dr. Beck has called a President's meeting on June 27, 1989 to which he has invited all of the presidents of the counties



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and specialty sections of CSMS.

Legislation: Dr. Beck asked Dr. Wetstone, Chairman of the CSMS Committee on Legislation, to give a brief report on some of the bills which CSMS was tracking. Dr. Wetstone reported on the following bills:

Nurses in Advanced Practice and Nurse Midwives and Prescriptive Authority: The bill passed with most of CSMS compromise language but included two last minute amendments. The first amendment was sponsored by United Technologies and allows Nurse Prescriptive Authority in employee clinics at sites with 2,000 or more employees. The second amendment grandfathered two specific nurses who did not meet the necessary qualifications. Dr. Wetstone acknowledged the many hours that Dr. Beck spent on this issue as the only physician on the task force.

Award of Damages to the Victims of Civil Wrongs: In response to a State Supreme Court ruling, it was legislated that a plaintiff's lawyer can suggest a dollar amount for damages, but only in his/her closing arguments. This was the only change this year in the Tort System.

AIDS Related Testing and Medical Information and Confidentiality: The bill passed with changes that CSMS had recommended.

Defintion of Podiatry: Failed. Compromise was reached allowing for discussions between CSMS and podiatrists.

Interest on Doctor's Bills: Recommitted.

Licensing of Psychologists: Passed.

Placement of Anabolic Steroids in the Schedule of Controlled Substances: Passed.

Working Hours of Interns and Resident Physicians: Failed.

Prescription Refills: Failed. Will be reintroduced next year.

Triplicate Prescription Forms: Failed.

Continuity of Access to Physical Therapy: Failed.

Out of State Physician Orders: Passed even though CSMS was joined by the State Department of Health Services in opposing it. Allows nurses to implement medical orders for a patient under the direction of an out of state physician. CSMS will seek repeal of this bill next year.

License Fee for Physicians: It was reported that the fee for physicians will be increased to \$450.00. All state licensing fees were increased as part of the 1989 tax package.

Following discussion, it was VOTED to ask the Legislative Committee to discuss the issue of including Physicians' Assistants into the Prescriptive Authority legislation and to report back to the Council for approval before any action is taken.

Report of the Executive Director

Tim Norbeck reported on the following items:

- (a) *Mandatory Medicare Assignment:* The Florida House Committee on Health voted 12-4 against mandatory assignment and it has been reported that the issue is probably dead for 1989.
- (b) *Washington Post - ABC News Poll:* The results of the poll gave physicians a 72% good or excellent rating regarding honesty and ethics. (The Congress and lawyers each received a 39% rating.)
- (c) *AMA Convention in Chicago:* He reported that one major item on the agenda will be the AMA Board's recommendation that the AMA endorse the concept of a phased in requirement that all employers, (initially only the larger ones), provide health insurance for all full-time employees, with coverage expanded over several years, and with a program of tax credits or other incentives to avoid adverse effects on employers. Also, there will not be any AMA dues increase for 1990.

Candidates for AMA Posts: CSMS will be running two candidates for AMA office. Dr. Kamens is running for Council on Medical Service and Dr. Rockford Yapp is running for the Resident slot on the AMA Board of Trustees.

- (d) *Federal Legislation:* Physician Payment Review Commission (PPRC) has recommended to Congress the establishment of a national physicians service expenditure target which would be linked to economic growth on a yearly basis. The rumors indicate that the Office of Management and Budget would require HCFA to withhold a percentage of each physician's fee for the first three quarters to insure that the target is not exceeded. AMA is adamantly opposed to the targets saying they would lead to expenditure caps and then to rationing of health care. Congresswomen, Nancy Johnson, who sits on the Ways and Means subcommittee that is considering the tactic, is committed to opposing expenditure targets in any form. The AMA points out that Canadian provinces experience with expenditure targets are disturbing and there is a growing wait for necessary surgery, degrading conditions for elderly hospital patients and there was unnecessary and premature deaths for some due to "queuing" up for treatment by surgeons constrained by target from operating in time.

HR 939: This bill that would prohibit Medicare payment for services rendered by an entity, when the referring physician has ownership interest, is being negotiated at this time. AMA, which opposes the bill, indicates that the bill's sponsor, Congressman Pete Stark, is willing to compromise by tightening the monitoring of such arrangements, but without prohibiting payment.

It is reported that Congress is planning to cut \$2.3

billion from the Medicare budget and physicians may have to absorb \$800 million of that cut.

Report of the Auxiliary President

Mrs. Joan Reed reported that the Auxiliary will be concentrating this next year on developing membership. Their two main projects of the upcoming year will be to assist the CSMS Physician Health Program and to revive the county auxiliary organizations.

Item Referred to Council From House of Delegates

The State of Connecticut Workers' Compensation Commission mailed a letter to all physicians concerning the implementation of Section 31-294 of the Connecticut General Statutes providing for an approved list of physicians furnishing medical services in workers' compensation cases. This item was referred to the Council by the House of Delegates for consideration and action.

Dr. Zeppieri explained the motivation for this letter stating that the State of Connecticut would like to increase its control in workers' compensation cases. He suggested that organized medicine respond to their call for assistance and recommended that the counties invite Commissioner Arcudi to speak to their boards.

It was VOTED to form a representative committee to meet with the Commissioner and report back to the Council. The committee will consist of Drs. Beck, Kamens, Zeppieri, Catrini and Fox.

Connecticut Coalition for Biomedical Research

Myron Genel, M.D., Professor of Pediatrics, Yale University, addressed the Council on the issue of organizing an all encompassing, pro-activist movement against the animal rights movement. He expressed the opinion that medical research is being besieged by a small, activist group whose aim is to end all biomedical research and that this group is very sophisticated in its tactics and is driving up the cost of research through regulations and bureaucratic impediments. He feels that this is a great threat to public safety and to the practice of medicine. He reported that the AMA is planning an equally sophisticated public relations campaign espousing the necessity of biomedical research from a proactive stance. Dr.

Genel distributed the AMA's Action Plan for the Council's review.

Dr. Genel's specific request of the Medical Society was to join and take leadership of a local effort to organize a Public Educational Coalition. Such a coalition would be separate from the lobbying coalition set up by the local pharmaceutical companies. Several universities in the state are interested and there are plans for an organizational meeting in September.

It was VOTED to send a representative to the September organizational meeting and to have that representative report back to the Council. In the interim, the Council will investigate the AMA action plan that was distributed by Dr. Genel.

Life Members

It was VOTED to receive the following list of Life Members as information:

Robert W. Cranston, M.D., Norwich (NL)
Philip S. Good, M.D. Waterbury (NH)
Carl G. Peterson, Jr., M.D., Wakefield, R.I. (W)
Ronald J. Pimpinella, M.D., Waterbury (NH)
Arthur G. Prangle, Jr., M.D., Greenwich (F)

Dates for Semi-Annual and Annual Meetings

It was VOTED to approve the following dates for the Semi-Annual and Annual meetings:

Semi-Annual Meeting, Wednesday, November 15, 1989

Annual meeting, Wednesday, May 9, Thursday, May 10, 1990

Dates of Next Council Meetings

Following are the dates of future Council meetings:

Wednesday, July 26, 1989

Thursday, September 7, 1989

Thursday, October 19, 1989

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on June 8, 1989. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.*

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

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INTERNAL MEDICINE

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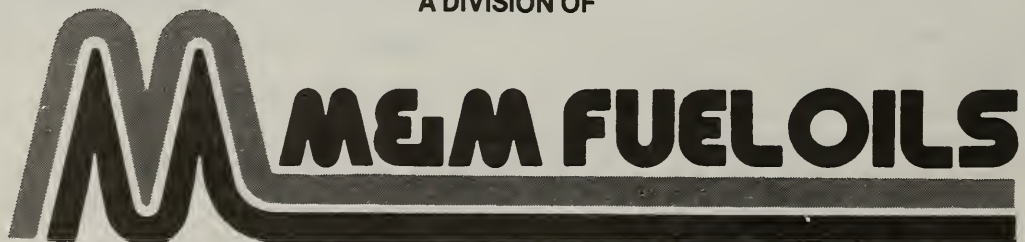
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Blunt Hollow Viscus Injuries of the Digestive Tract: A Poorly Recognized Phenomenon

WALTER E. LONGO, M.D., LINDA C. DEGUTIS, M.S.N.,
AND CHRISTOPHER C. BAKER, M.D.

ABSTRACT—A review of records from admission to the trauma center at Yale-New Haven Hospital for a five year period (July 1981 through June 1986) revealed 41 blunt hollow viscus injuries in 31 patients. Organs injured included small intestine (18), large intestine (14), duodenum (6), stomach (2), and gall bladder (1). The most accurate predictors of blunt hollow viscus injury were peritoneal lavage (91%, n=14) and abdominal tenderness (50%). Seventeen patients underwent early celiotomy with morbidity and mortality rates of 16% each. Nonetheless, 13 patients had delay in diagnosis with substantially higher morbidity (46%) and mortality (31%). Blunt hollow viscus injuries are uncommon, are difficult to diagnose, and can lead to major morbidity and mortality when diagnosis is delayed.

Introduction

ALTHOUGH several large series have focused on penetrating abdominal injuries¹ as well as blunt injuries to a solid organ^{2,3} (spleen, liver, kidney), relatively few studies have investigated hollow viscus injuries to the digestive tract due to blunt trauma. Rupture of a hollow gastrointestinal organ occurs in 5% to 15% of patients sustaining serious blunt trauma to the abdomen.⁴ These types of injuries represent a diagnostic dilemma to most surgeons because of the lack of major initial blood loss, nonspecific physical findings, and the frequent association with extraabdominal injuries.^{5,6,7} Although blunt hollow viscus injuries represent a small portion of all blunt abdominal injuries, they are seen with increasing frequency and are associated with significant morbidity and mortality, primarily due to delay in diagnosis and treatment. Delays in diagnosis of hours or days after the initial injury often result in peritonitis, abscess formation, fistulization, or intestinal necrosis.

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To understand further the occurrence and management of these injuries, all patients admitted to Yale-New Haven Hospital Trauma Center who sustained an injury to the stomach, small bowel, large bowel, and gallbladder as a result of blunt trauma were reviewed for a five-year period.

Materials and Methods

The records of all patients with the diagnosis of blunt trauma to the stomach, small bowel, large bowel, or gallbladder admitted to the Yale-New Haven Hospital (YNHH) from 1 July 1981 to 30 June 1986 were reviewed. A total of 31 patients who sustained 41 blunt hollow viscus injuries of the digestive tract were retrospectively reviewed. Data obtained included demographic data, mechanism of injury, presence or absence of hypotension on admission, physical findings, the presence of associated intraabdominal as well as extraabdominal injuries, and the timing of the diagnosis and treatment. Results of peritoneal lavage, plain films of the abdomen, chest, or pelvis, computerized tomographic (CT) scanning and other contrast studies, and laboratory data were analyzed. Outcome, complications, and mortality were evaluated. During the period of this review over 4,000 patients were admitted to YNHH with blunt trauma.

Results

Types of Injuries

There were 41 blunt hollow viscus injuries among 31 patients. There were 25 males (81%) and six females (19%). Twenty-four patients (74%) were white and seven patients (26%) were nonwhite. The age of the patients ranged from 13 to 64 years with a mean age of 38.1.

The most common mechanism of injury was a motor vehicle crash (n=18). Sixteen of these 18 patients had not been wearing seat belts. Three patients were involved in motorcycle crashes, and none of these patients had been wearing helmets. Four patients were pedestrians, all were struck by automobiles. Four patients were assaulted: one received multiple blows to the abdomen; one had been hit by a two-by-four board; one was thrown onto a

stationary table; and one had been hit by a heavy object. Of the remaining patients, one had fallen 20 feet, landing on a carpenter's bench; another patient had been pinned between a fork lift and heavy boxes in an industrial accident.

Site of Injury and Treatment

The anatomic sites of injury are listed in Table 1. There were two gastric injuries, both perforations along the greater curvature; one was associated with a ruptured left hemidiaphragm. Both were oversewn and gastrostomies created. There were 24 small bowel injuries: six to the duodenum; 11 to the jejunum; and seven to the ileum. Two duodenal transections occurred in the second portion, and were treated by segmental duodenectomy and duodenojejunostomy. Three duodenal perforations were found, two in the first portion and one in the second portion. In all three patients the duodenal defect was closed. An 18-year-old male who had been assaulted developed a duodenal hematoma and was treated non-operatively; he was discharged 14 days later. Of the 11 jejunal injuries, nine were proximal and two were distal.

Table 1
Blunt Hollow Viscus Injuries

Site	No.
Gastric	2
Duodenal	6
Proximal Jejunum	9
Distal Jejunum	2
Proximal Ileum	1
Distal Ileum	6
Right Colon	6
Transverse Colon	3
Left Colon	5
Gallbladder	1
Total	41

There were five perforations, four transections, and two devascularizations. All 11 had small bowel resections and primary anastomoses. Two jejunal injuries were associated with concomitant ileal perforations. All but one of the ileal injuries occurred in the terminal ileum. Four were transections and two were perforations; all were treated with ileal resection. One ileal injury was secondary to devascularization which included the right colon, and an ileocolectomy was performed. One patient, involved in a high-speed motorcycle crash, avulsed his gallbladder with an associated major liver laceration. He died of exsanguination after a short postoperative course.

Table 2
Positive Findings Associated with Blunt Hollow Viscus Injury

Clinical Findings	No.	Accuracy
Tenderness	15	50%
Peritoneal Signs	9	28%
Shock	6	20%
Diagnostic Tests		
Peritoneal Lavage	14	91%
Free Air on Upright Film	12	25%
Contrast Study	1	100%

There were 14 large bowel injuries; six right colon injuries; three transverse colon injuries; four left colon injuries; and one sigmoid injury. Of the six right colon injuries, four had major devascularization. Two of these patients exsanguinated intraoperatively, and the other two underwent right hemicolectomy, ileostomy, and transverse colon mucous fistula. Two of the right colon injuries were perforations, one at the appendix, for which appendectomy was performed. The other patient underwent cecectomy and an ileocolostomy was created in the ascending colon. Of the three transverse colon injuries, two were perforations. One was oversewn while the other was treated by a sleeve resection and primary anastomosis. The third transverse colon injury was a serosal tear which was oversewn. There were four left colon injuries. One was a major devascularization requiring left colectomy, colostomy, and mucous fistula. The other three were transections, and two underwent segmental resection, colostomy, and mucous fistula. The third patient underwent repair and exteriorization, only to develop a prolapse that required resection, colostomy, and mucous fistula. The only sigmoid injury was a perforation from a seat belt injury requiring sigmoid resection and sigmoid colostomy.

Diagnostic Methods

The findings associated with a blunt hollow viscus injury are listed in Table 2. The most common findings were abdominal tenderness, free air on plain upright film, and a positive peritoneal lavage, which was usually positive secondary to an associated intraabdominal injury. Peritoneal lavage was considered positive by showing red cells (>100,000/mm³) in 13, and white cells (>500/mm³) in three (amylase was not routinely tested). CT scans were obtained in three patients. Two CT scans obtained early, showed solid organ injury and led to exploratory laparotomy at which time unsuspected hollow viscus injuries were identified. The other patient had a CT scan 14 days after injury that showed a central abdominal fluid collection related to a small contained perforation of the jejunum. There were 23 associated intraabdominal injuries and 17 associated extraabdominal injuries among 18 patients. Liver and spleen injuries were the most common associated intraabdominal injuries, and skeletal injuries were the most common extraabdominal associated injuries (Table 3).

Eighteen patients had a straightforward picture and presented either in shock, with a surgical abdomen, or had a positive peritoneal lavage that brought them to the operating room where a hollow viscus injury of the digestive tract was identified. Four patients with equivocal abdominal findings were found to have free air on upright chest films and were subsequently surgically explored. One patient (treated nonoperatively) had a large duodenal hematoma recognized on gastrograffin swallow.

Thirteen patients had a delay in diagnosis (90 minutes to 14 days) of their hollow viscus injury with the injury

found at celiotomy. These patients either developed fever, a surgical abdomen, or were found to have free air on subsequent plain films. One patient had a mesenteric devascularization of his terminal ileum and presented with fever, abdominal pain, and tenderness 14 days after a motor vehicle crash. The average delay in diagnosis was 26 hours with a range of 90 minutes to 14 days.

Table 3
Associated Injuries

Abdominal		Extrabdominal	
Spleen	7	Skeletal	7
Liver	6	Thoracic	4
Pancreas	3	Neurological	13
RH	2	Vascular	2
Kidney	2	Facial	1
Diaphragm	2		
Bladder	1		

Morbidity and Mortality

There were seven deaths (22%). Three patients died from sepsis and multiple organ failure as a direct consequence of their hollow viscus injury. Three patients died from exsanguination and one from a central nervous system injury as well as his associated hollow viscus injury. Among nine patients, there were 21 complications: prolonged ileus, abscess formation, and wound infection being the most common (Table 4).

Among the 13 patients who had a delay in diagnosis, four showed free air on subsequent chest films. One of these patients had a distended, nontender abdomen and was in a coma from an intracerebral hemorrhage. The other three patients had progressive abdominal pain and tenderness, and two had fever above 38° C. Of the remaining nine patients who had a delayed hollow viscus injury without evidence of free intraperitoneal air, eight initially had abdominal tenderness with voluntary guarding to deep palpation that later progressed either to localized tenderness or to generalized peritonitis. Seven of these nine patients had fevers above 38° C, and all had serial white blood cell counts above 12,000 with a left shift. The one patient whose delay was 14 days developed an acute onset of abdominal pain with an acute abdomen two weeks after injury. He had a walled-off jejunal perforation at the time of exploratory celiotomy. Among the 18 patients without a delay in diagnosis, a positive peritoneal lavage led to laparotomy in

Table 4
Morbidity

Prolonged Ileus	8
Abscess	4
Wound Infection	3
Pneumonia	2
Evisceration	1
Prolapsed Bowel	1
Pancreatitis	1
Arrhythmias	1
Total	21

14. The other four patients either showed free air or an acute abdomen that prompted an operation.

Delay in diagnosis and treatment had a substantial effect on morbidity and mortality in this series. A comparison for patients with and without delay is shown in Table 5. The number of patients is too small for statistical analysis, but a clinical trend can be seen. Delay in operative intervention in patients with blunt hollow viscus injuries led to a substantial increase in both morbidity (from 16% to 46%) and mortality (from 16% to 31%). Patients with delay did not have localizing signs initially and/or did not have associated injuries that would lead to celiotomy.

Discussion

The surgeon's failure to manage abdominal injuries successfully accounts for the majority of preventable deaths following multiple injuries.⁸ The incidence of abdominal hollow viscus injuries following blunt trauma remains between 1% and 15%. Nevertheless, these types of injuries remain under-recognized, are often difficult to diagnose, and are associated with high morbidity and moderate mortality.

There are many theories to explain why these injuries occur, including crush injuries between the vertebral column and the anterior abdominal wall,⁹ sudden increases in the intraluminal pressure of the bowel,¹⁰ and tangential tears at fixed points along the bowel.¹¹ Most of these injuries today result from alcohol-related motor vehicle crashes and are associated with multisystem injuries.¹²

Table 5
Timing of Operative Intervention

	No Delay	Delay
Number of patients (% of total)	17 (58%)	13 (42%)
Morbidity (%)	3 (16%)	6 (46%)
Mortality (%)	3 (16%)	4 (31%)

Samuel Annan, in 1837, was the first to report a case of intestinal rupture secondary to blunt trauma in America.²⁶ Since then many reviews concerning gastric,^{13,14} duodenal,^{15,16} jejunal-ileal,^{11,17,18} colorectal,^{19,20,21} and gallbladder^{22,23} injuries in both adults and children secondary to blunt trauma have been written. The 31 patients covered in the current review demonstrate the age, sex, mechanism, morbidity, and mortality distributions that are seen in other reviews. Although peritoneal lavage was only performed in 14 of the 31 patients in this study, it was 91% accurate. This study shows, however, that delays in diagnosis are still common.

As has been shown by Olsen²⁴ and also by Kovacs,²⁵ serum amylase determinations are of no value and are unreliable in diagnosing blunt hollow viscus injuries. Plain films of the chest or abdomen may show evidence of pneumoperitoneum or retroperitoneal air either initially or on subsequent roentgenograms. Physical examination may be unreliable because of central nervous system

injury, alcohol intoxication, or narcotic abuse. Often physical examination may not show the signs of an acute abdomen or peritoneal injury or inflammation. Serum hematocrit is often stable because blood loss is minimal.

Because of the lack of a specific test for blunt hollow viscus injuries, repetitive clinical assessment of these patients remains the most important aspect of their care. In this study of 30 patients who underwent operative intervention, 41% had late celiotomy owing to a lack of specific signs of a hollow viscus injury. These patients sustained a 46% morbidity and 31% mortality because there was a delay in diagnosis of their injury (Table 5).

Since the overwhelming majority of patients with blunt hollow viscus injuries are young and healthy, with a minimal risk of a negative laparotomy, it would appear that early laparotomy would far outweigh the morbidity and mortality associated with delay.

Conclusion

This study confirms that delay in diagnosis of blunt hollow viscus injuries contributes substantially to a high morbidity and mortality following these injuries. These data lead to five conclusions: First, that blunt hollow viscus injuries are uncommon: we were able to find 41 injuries in 31 patients out of approximately 4,000 admissions. Second, standard clinical findings and diagnostic tests are not specific for blunt hollow viscus injuries. Third, delay in diagnosis leading to late celiotomy is common (41%). Fourth, morbidity and mortality are high in these patients and are increased when there is a delay in diagnosis and treatment. Finally, to diagnose and treat blunt hollow viscus injuries, a high index of suspicion and early celiotomy are recommended in patients with major blunt abdominal trauma in order to insure early and expedient treatment of blunt hollow viscus injuries.

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Lung Cancer Presenting as Small Bowel Perforation

JAMSHID SHIRANI, M.D. AND JOHN W. BRACKETT, M.D.

ABSTRACT—A case of squamous cell carcinoma of lung presenting with acute abdominal pain secondary to jejunal perforation at the site of a solitary metastatic lesion is presented. The literature regarding this unusual presentation of lung cancer is reviewed.

Introduction

LUNG cancer is the number one cause of cancer death in the United States.¹ The generally poor prognosis of this cancer is mainly related to the presence of advanced disease at the time of an initial presentation.² Although lung cancer can affect any organ, it more predictably affects lymph nodes, bone, liver, brain, and adrenal glands. The reason for preferential involvement of these organs is not entirely clear. Among the histologic subtypes of lung cancer, squamous cell carcinoma has the lowest incidence of extrapulmonary metastatic spread at the time of diagnosis.³ In addition, the gastrointestinal tract is among the unusual sites of metastasis from a lung tumor.⁴ When lung cancer metastasizes to the gut, it is usually in the setting of an end-stage, widely metastatic tumor.⁵

Case Report

A 60-year-old white male presented with sudden onset of abdominal pain, dizziness, and perspiration. He had a history of severe restrictive lung disease and pulmonary parenchymal scarring related to chemical exposure at work, chronic heavy smoking, and several bouts of pneumonia in the past. There was no recent change in his chronic respiratory symptoms of productive cough and dyspnea. Nonspecific abdominal discomfort had been noted for a few weeks prior to presentation.

On admission, the patient was afebrile with a blood pressure of 110/70 mm Hg, pulse rate of 130 per minute, and respiratory rate of 22 per minute. He appeared chronically ill with marked clubbing of fingers, coarse crackling rales at both lung bases, and a rigid, tender abdomen. Extensive bullous disease and parenchymal scarring of the lungs was seen on roentgenogram. The

hemoglobin level was 13.2 gm/dl, amylase and lipase levels were normal, and arterial blood gases showed a PO₂ of 93 and a PCO₂ of 21 torr on 2 L of supplemental oxygen by nasal cannula.

At operation a round, hard, white nodule was found in the proximal jejunum, 5 cm in diameter, with a perforation of 0.3-0.4 cm in the center. Pathological examination showed metastatic squamous cell carcinoma. No other intraabdominal metastatic foci were found. Post-operative recovery was complete. Subsequent urinalysis and liver function studies were normal; the sputum on cytological examination showed malignant cells. A computerized tomographic scan of the chest revealed a 2 cm solid nodule in the mid-left lung zone and a large pericardial effusion. This remained hemodynamically insignificant. The patient was discharged without further therapy. He was found unresponsive at home five weeks later and died 24 hours after admission to the hospital. The cause of death was presumed to be metastases to the central nervous system. No evidence of cardiac tamponade was found on clinical evaluation. Permission for an autopsy was denied.

Discussion

Small intestinal perforation secondary to metastatic lung cancer has been reported in 11 cases previously. In six of these cases the diagnosis of lung cancer had been made prior to presentation with acute abdominal pain. These patients had been receiving therapy for their primary disease at the time of intestinal perforation.⁶⁻¹¹ Four of these six patients had squamous carcinoma,^{6,7,9,11} one had giant cell anaplastic carcinoma⁸ and the histology of the primary lung cancer in the last patient was adenocarcinoma.¹⁰ Of all reported cases, five had not been known to have lung cancer prior to presentation with acute abdominal symptoms.¹²⁻¹⁶ The clinical and pathologic characteristics of these patients together with the present case are summarized in Table 1.

Our patient is the youngest of the reported cases with previously undiagnosed lung cancer. Five of these patients were male. Most tumors had metastasized to jejunum, possibly because this represented the greater surface area of this segment of small intestine. Sites of the primary tumors are distributed randomly between right

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and left lung as well as upper and lower lobes. Sixty-six percent of the primary tumors (4/6) were squamous cell carcinomas. This may represent a pattern of metastasis peculiar to this histologic type of lung cancer. Intestinal perforation appears to portend a poor prognosis with patients surviving less than seven weeks from the time of surgery.

Conclusion

Small bowel perforation is a rare presentation of lung cancer. It should be considered in the differential diagnosis of patients with acute abdominal symptoms especially in those at high risk for lung cancer. This indicates a terminal event even in the absence of other identifiable metastases. Squamous cell carcinoma has been the predominant histologic type in the reported cases.

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FOR WOMEN PHYSICIANS:

AMWA - BRANCH NO 7 - MEETING

All AMWA members, and interested women physicians, of the State of Connecticut, are invited to attend the Annual Meeting of the American Medical Womens Association, Branch No 7, at the Farmington Marriott Hotel, 15 Farmington Springs Rd., Farmington, CT (off exit 37 on I-84).

Date: Wednesday, September 27, 1989
 6:30 PM Discussions and election
 7:30 PM Lecture by Dr. Yolanda Pena, Neurologist
 8:30 PM Dinner

All Connecticut women physicians are invited
Please reply by September 18, 1989, at (203) 423-1120

AIDS Cases with No Identified Risk: Artifact or Reality?

The Connecticut Example

JULIA WANG MILLER, PH.D. AND MARJORIE EICHLER, R.N., M.PH.

ABSTRACT—Connecticut's 66 AIDS cases initially reported with no identified risks (NIRS) were reviewed and intensively investigated. Investigation resulted in reclassification of 45 cases (68.2%) to categories of known risk; one case (1.5%) was misdiagnosed as AIDS. Twenty cases (30.3%) remain NIRS because no risk could be established at this time. Evidence that NIRS represent reporting artifact, rather than unknown or new modes of transmission, was found. (1) NIRS are cases for which information on sexual behavior is highly sensitive or difficult to obtain. After investigation, 72% of reclassified Connecticut NIRS were determined to have risks related to sexual transmission. (2) The percentage of NIRS fluctuates according to reporting source and method of investigation. Within Connecticut, major reporting sources vary from a high of 15% to a low of 0% NIRS among their cases. The most effective method for establishing risks was to obtain information from reporting sources.

Introduction

CASES with no identified risk are 3.2% of 79,823 United States cases of the acquired immunodeficiency syndrome (AIDS) reported as of 5 December 1988, and 2.0% of 989 Connecticut AIDS cases reported as of 2 December 1988. Do these cases represent unknown modes of transmission, or are they artifacts of reporting? Our investigations provide some evidence on this question.

In the State of Connecticut, surveillance of CDC-defined AIDS cases began in 1981 with the first reported case and continues to the present. As part of routine AIDS surveillance activities, the investigation of cases initially reported with no identified risks (NIRS) is carried out on an ongoing basis with the cooperation of reporting sources and patients willing to be interviewed.

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Along with other states and reporting areas, we participated in the CDC's recent review of NIRS reported through 30 September 1987.¹ In addition, we conducted our own review and intensive investigation of NIRS reported through 2 December 1988. The results and implications are discussed in this paper.

Methods

The CDC's draft protocol for investigation of NIRS has been helpful in developing procedures for our review.² We followed a variety of strategies. Report forms and other official documents, such as death certificates and medical records, were reviewed. Reporting sources were contacted for information or leads. If definitive evidence on the patient's risk could not be obtained by these means, patients were contacted and interviewed, with the physician and patient's consent. The CDC's NIR questionnaire was used to structure the interview; the questionnaire has extensive items on medical, sexual, and drug-using history. Informal fact-finding during the interview has also proved useful. In the rare situation where the patient was not available and it was appropriate to contact the family, free-form interviews with family members were conducted.

For the purpose of analysis, cases initially reported as NIRS were divided into two groups according to the outcome of the investigation. (1) "Solved" cases are cases misdiagnosed as AIDS or cases for which a known risk is identified. (2) "Unsolved" cases are those for which no risk is found.

Results

Comparing Connecticut NIRS with other adult cases for which a risk was known at the time of report, we found that a slightly higher proportion of NIRS are female. Otherwise, they have similar demographic characteristics (Table 1).

In addition, we compared NIRS to other adults in terms of human immunodeficiency virus (HIV) antibody status and occupation. Eighty percent of unsolved NIRS and 68% of solved cases were known to have positive

confirmed HIV antibody test results. Other adult cases were 66% HIV antibody positive. The remaining cases did not have such tests or data are missing. The percentage of health care workers among NIRS was higher than among other adult cases. Twenty-five percent of unsolved NIRS and 9% of solved cases were health care workers as compared to 5% of other cases. However, among the five *unsolved* NIRS who were health care workers, all but one were maintenance or kitchen workers. The remaining case worked with patients, but not in a high-risk profession.

TABLE 1
Demographic Characteristics of Cases Initially Reported with No Identified Risks (NIRS) and Cases Initially Reported with Known Risks: Adult AIDS Cases in Connecticut as of 2 December 1988

Total Adult Cases = 957			
NIRS (66, 6.9% of total)		Cases with Known Risks (891, 93.1% of total)	
No Risk Found/"Unsolved" (20, 2.1% of total)		Risk Found/"Solved" (46, 4.7 of total)	
AGE			
Range	27-69	20-68	20-81
Median	39.0	36.5	35.0
Mean	40.1	39.5	36.8
SEX, N (Col%)			
Male	16 (80.0)	32 (69.6)	728 (81.7)
Female	4 (20.0)	14 (30.4)	163 (18.3)
RACE, N (Col%)			
White	11 (55.0)	20 (43.5)	418 (46.9)
Black	6 (30.0)	17 (37.0)	325 (36.5)
Hispanic	3 (15.0)	9 (19.6)	142 (15.9)
Other/ UnKnown	—	—	6 (0.7)

The outcome of our investigations was that many cases were successfully solved. Of the 66 NIRS reviewed, 45 (68.2%) were found to have a known risk, and one case (1.5%) was misdiagnosed as AIDS. However, 20 (30.3%) remain unsolved at this time (Figure 1).

Sexual transmission was particularly important among Connecticut's NIRS. Among the "solved" cases, the great majority (72%) were either homosexual, bisexual, or heterosexual transmission cases (Table 2). Heterosexual cases were most frequently sex partners of intravenous drug users. Most cases which are currently "unsolved" are cases of suspected sexual transmission. These patients report a history of sexually transmitted diseases or sex with female prostitutes (Table 4). We have circumstantial or hypothetical information on some unsolved cases, but nothing definitive enough to reclassify the patient as one with a known risk.

For the most part, cases were solved by obtaining information from reporting sources (82.6%), rather than from interviews with patients (13.0%) (Figure 1). Not all interviews resulted in finding a risk. Of 14 patient interviews conducted, six succeeded in finding a known risk; six failed to solve the case; two interviews failed to establish risks, which were later provided by reporting sources. Therefore, the success rate of patient interviews was 42.9% (6/ 14).

FIGURE 1
Outcome of Review of Connecticut Cases Initially Reported as NIRS

I. 66 AIDS Cases Initially Reported as NIRS	
A. No Identified Risk Found/"Unsolved"= 20 (30.3% of I.)	B. Risk Found/"Solved"= 46 (69.7% of I.)
(1) Currenly under investigation = 6 (30.0% of A.)	(1) Information from reporting source(s)*= 38 (82.6% of B.)
(2) Patients interviewed = 6 (30.0% of A.)	(2) Patients interviewed = 6 (13.0% of B.)
(3) Patients died before interview = 8 (40.0% of A.)	(3) Information from official documents = 1 (2.2% of B.)
	(4) Patient misdiagnosed as AIDS = 1 (2.2% of B.)

* Two of these cases were also interviewed; however, no information was obtained from the patient. Information was later provided by reporting sources.

Time trends for cases initially reported as NIRS and "unsolved" cases are shown in Table 3. Connecticut's percentage of NIRS is relatively steady over the last years of report at 6% to 7%. After review and intensive investigation, cases remaining NIRS or "unsolved cases" decreased from their initial levels. For cases reported from 1981 through 1985, the percentage of NIRS decreased from 9.5% to 2.4% following investigation. In 1986 and 1987, the percentage dropped from 6.0% to 1.2% and 4.2% to 1.5%. Among 1988 cases, the 5.8% of cases first reported as NIRS is currently 2.8%.

An analysis of Connecticut NIRS by major reporting source (those first diagnosing 10 cases or more) indicates that some sources have significantly higher proportions of NIRS—particularly unsolved NIRS—than others. Proportions of cases first reported as NIRS range from 15% to 0% among the 18 major sources. The proportion of "unsolved" cases among these sources ranges from 14% to 0%. (Grouped data are available upon request.)

Discussion

The similarity of demographic characteristics between NIRS and cases reported with known risks suggests they represent the same kind of patient. We believe the greater proportion of female NIRS, however, may be due to the difficulty of questioning these patients or of establishing risks for their male sex partners.

With regard to HIV antibody test results, NIRS are known to have positive confirmatory tests more frequently than other adult cases; in fact, unsolved NIRS have a much higher percentage of positive tests than other cases. Therefore, it is unlikely that NIRS represent misdiagnosis any more frequently than other reported cases. Nonetheless, early in the epidemic when antibody tests were not available or routinely used, misdiagnosis may have been more likely.

NIRS were found more frequently to be health care workers than were other cases. On close examination, however, occupational exposure is unlikely to be the mode of transmission for these cases. Among the five

health care workers who remain unsolved NIRS, either they were not involved in direct patient care or did not perform high-risk procedures. As is true for many NIRS, other risks were strongly suspected, but could not be substantiated.

The successful reclassification of many NIRS shows that these cases represent missing information or information which is difficult to obtain. The preponderance of risks due to sexual transmission among “solved” NIRS further emphasizes the sensitive nature of information on sexual behavior. Even among “unsolved” cases, sexual transmission is suspected for the majority. However, one must be cautious about anecdotal evidence that can mislead an investigator. For example, claims to having sex with female prostitutes have been found to shield intravenous drug use or homosexual practices.³

TABLE 2
Modes of Transmission for NIRS with Risk Found and Cases Initially Reported with Known Risks: Adult AIDS Cases in Connecticut as of 2 December 1988

<i>NIRS with Risk Found = 45 Cases with Known Risks = 891</i>		
<i>Mode of Transmission, N (Col%)</i>		
Homosexual/bisexual males	16 (35.6)	381 (42.8)
Intravenous drug user	11 (24.4)	352 (39.5)
Homosexual/bisexual male and intravenous drug user	—	66 (7.4)
Heterosexual cases	17 (37.8)	56 (6.3)
Partner of IV drug user	12 (26.7)	38 4.3)
Other Heterosexual risk	5 (11.1)	18 (2.0)
Transfusion/hemophiliac	1 (2.2)	36 (4.0)

NOTE: Of the 46 solved cases, one was misdiagnosed as AIDS and, therefore, is not included in the analysis of Mode of Transmission.

Unlike national trends which show increasing percentages,¹ Connecticut’s percentage of cases initially reported as NIRS remains relatively stable, although it is somewhat high. In the future, we hope this percentage will decline as the result of our active collaboration with sources, who are asked to investigate patients’ risks as thoroughly as possible before reporting cases to us. Connecticut’s overall percentage of current “unsolved” NIRS is 2.1% of adult cases. 1988’s percentage of unsolved NIRS (2.8%) is expected to decline to match those of previous years once cases under active investigation are resolved.

TABLE 3
Connecticut NIRS by Year of Report and Investigation Status

<i>Total Adult Reporting year</i>	<i>Cases Initially Reported as NIRS</i>	<i>Cases Remaining NIRS After Review (“Unsolved”)</i>
1981-85	169	16 (9.5)
1986	166	10 (6.0)
1987	263	19 (7.2)
1988	359	21 (5.8)
(1/1-12/2)		
Total	957	66 (6.9)
		20 (2.1)

* It is anticipated that the percentage of NIRS reported in 1988 will decrease further than 2.8% when cases currently under active investigation are resolved.

Variations in percentages of NIRS among reporting sources and by method of investigation further support our view that these cases represent reporting artifact, and not new or unknown modes of transmission. Ten years into the epidemic, no new modes of transmission have been found,⁴ other than those already firmly established.

TABLE 4
“Unsolved” NIRS with Self-Reported History Suggestive of Sexual Transmission

<i>History*</i>	<i>Number</i>	<i>Percent</i>
STDS**	5	25.0
Sex with female	4	20.0
Prostitutes		
Circumstantial evidence	3	15.0
No evidence	8	40.0
Total	20	100%

* Categories are hierarchically ordered.

** Includes syphilis, gonorrhea, genital herpes, venereal warts, or pubic lice.

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Important Advances in Clinical Medicine

Otolaryngology/Head and Neck Surgery

The Scientific Board of the California Medical Association presents the following inventory of items of progress in otolaryngology/head and neck surgery. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers, or scholars to stay abreast of these items of progress in otolaryngology/head and neck surgery that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Otolaryngology/Head and Neck Surgery of the California Medical Association and the summaries were prepared under its direction.

Needle Aspiration of Peritonsillar Abscesses

PERITONSILLAR abscess is the most common deep infection of the head and neck. It develops in the potential space between the tonsillar capsule and the superior constrictor muscle. Untreated, it can lead to more serious life-threatening deep-space infections of the retropharyngeal or pterygomaxillary space. In the past, standard recommended surgical therapy consisted of acute incision and drainage or acute abscess tonsillectomy. More recently, needle aspiration as the sole surgical intervention has proved to be effective in treating this disease.

The aspiration is carried out using an 18-gauge needle at a point about midway between the base of the uvula and upper alveolar ridge. A spinal needle may be used if trismus prevents the use of a standard 1½-inch needle. The abscess will resolve in about 90% of the patients with a single aspiration, with the other 10% resolving on one or two additional aspirations. Recovery from the disease is comparable to that of incision and drainage.

The advantages of this technique are its minimal morbidity, its cost-effectiveness, and its ease of performance. Although treatment of this process still remains within the purview of a head and neck specialist, generalists have been taught to do this procedure in geographic areas where an otolaryngologist may not be readily

available. Culture and sensitivity of the aspirate yields *Peptostreptococcus*, group A streptococci, *Peptococcus*, and *Fusobacterium* in 75% of the cases. Penicillins or cephalosporins will provide adequate chemotherapeutic coverage in most cases. In two separate studies, however, culture results did not affect the outcome of the disease. Routine bacteriologic evaluation of the aspirate is then probably unnecessary and its elimination could contribute to additional cost-effectiveness. Admitting to hospital is unnecessary except when additional health considerations, such as altered immunity or dehydration, complicate the process.

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Scapular Osteocutaneous Free Flap for Mandibular Reconstruction

RECONSTRUCTING mandibular defects following trauma or cancer surgery has long been a challenging problem. While lateral defects may arguably be

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left unreconstructed or later undergo a staged reconstruction, defects of the anterior arch of the mandible cause such severe cosmetic and functional disabilities that immediate reconstruction is desirable. Preserving the normal facial profile and maintaining oral sphincter competence are of immense benefit to these patients.

Experience with nonvascularized bone grafts from ilium or rib has shown prohibitively high infection and graft loss rates when these grafts are placed in a field contaminated with saliva. They are more successful when used in a staged fashion where an entirely extraoral approach is possible. Using various metal reconstruction plates, frequently in conjunction with a pedicled myocutaneous flap, to bridge and stabilize anterior defects is another strategy. This approach, however, is also prone to problems related to infection, leading to plate exposure and extrusion, particularly in previously irradiated patients.

The scapular osteocutaneous flap is based on the circumflex scapular artery (a branch of the subscapular artery) and its accompanying veins. Direct perforators from fascia supply the skin, so the flap is thin and pliable. Because blood supply to skin and bone is separate, the bone graft and skin paddle can be positioned in a variety of complex three-dimensional relationships. Both skin and intraoral mucosa can be replaced simultaneously if portions of the flap are de-epithelialized.

The 6-cm vascular pedicle is of sufficient length to reach recipient vessels in the neck, and the vessel caliber is typically 2 mm, sufficient to ensure good patency rates. A 2- to 3-cm width of corticocancellous bone 12 to 14 cm long can be taken from the lateral border of the scapula. This is adequate for defects reaching from one angle of the jaw to the opposite angle. Reattaching the teres muscles and active physical therapy postoperatively will minimize donor-site morbidity. One or two appropriately placed osteotomies allow contouring of the bone to the necessary curvature for anterior arch replacement. Small compression plates secure the bone graft in position.

Standard microvascular techniques of end-to-end or end-to-side anastomosis are used to reestablish perfusion to the flap. Although a microvascular flap transfer adds several hours to an already lengthy procedure, using a two-team approach allows the flap to be simultaneously harvested while primary tumor removal and neck dissection are done.

The two published clinical series using the scapular osteocutaneous flap for mandibular reconstruction report no flap failures and a 90% bony union rate in a total of 31 patients. Our own early clinical experience certainly supports this. The additional time and cost involved in doing a one-stage, vascularized reconstruction are justified when subsequent hospital admissions and surgical procedures can be obviated, delays in initiating planned combined radiotherapy can be avoided, and

patients can have immediate restoration of appearance and function.

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Advances in Chemoprophylaxis for
Head and Neck Surgical Wound Infections

PATIENTS undergoing procedures of the head and neck are susceptible to wound infection because there is frequent contamination from bacterial flora of the upper aerodigestive tract. Studies have conclusively shown that using antibiotic prophylaxis substantially reduces this risk. More recent studies have provided further refinements in the guidelines for antibiotic prophylaxis in head and neck operations. Prolonged antibiotic administration, a commonly used practice, has no added benefit compared with short-term prophylaxis. It has now been clearly shown that the rate of wound infection for procedures that do not involve exposure of the aerodigestive tract—that is, clean wounds—is sufficiently low not to warrant routine antibiotic prophylaxis. Both of these observations represent substantial cost reductions. Risk factors that previously were thought to contribute to the development of wound infection, such as preoperative radiotherapy and chemotherapy, do not appear to be significant. Factors that carry the highest risk include the stage of the disease and the complexity of the operative procedure.

The choice of antibiotic that provides the best protection against wound infection remains controversial. Some studies support the use of broad-spectrum agents effective against most gram-positive aerobes including staphylococci and many gram-negative organisms. Other studies support the use of third-generation cephalosporins that are most effective against anaerobic organisms. These newer third-generation cephalosporins, however, are less effective against gram-positive and gram-negative aerobic organisms. A recent study indicated the etiologic importance of anaerobes in the development of head and neck wound infections. The combination of metronidazole, highly specific for anaerobes, and cefazolin was associated with a significantly lower infection rate when compared with prophylaxis with cefazolin alone (9.5% versus 18.6%). An added advantage of this combination is that newer antibiotics can be used therapeutically should wound infection develop.

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Moving Platform Posturography

EVALUATING dizziness and balance disorders can be a complex challenge. The results of traditional neuro-otologic workups, which rely primarily on tests of the vestibuloocular reflex, are often negative in these patients. Because the somatosensory, visual, and vestibular systems all contribute to postural control in humans, Romberg test results are also often inconclusive. A new test of postural control, moving platform posturography, has been developed and is proving helpful in diagnosing and treating balance disorders.

Moving platform posturography tests a patient's ability to maintain balance in conditions with and without normal somatosensory and visual information for postural control. In addition to evaluating the patient's ability to use vestibular information to control posture, the test also assesses a patient's motor coordination, strength, quickness, and adaptability in the face of challenges to balance.

Extensive work has been done to establish normative data and patterns seen in diseased states. In one study of 80 patients with known peripheral vestibulopathies, 76 patients (95%) showed normal sway patterns in standard Romberg tests. Of the same group of patients, however, 77 (96%) had significant impairments in postural stability when normal somatosensory and visual cues for postural control were unavailable. Another study used moving platform posturography to study 74 patients aged 65 and older who complained of dizziness or imbalance. Almost all of these patients had signs of peripheral or central vestibulopathies, and 59 (80%) showed increased body sway in test conditions without normal visual and somatosensory cues for postural control.

In addition to providing information for diagnosis, this test can be used to evaluate the functional balance capacity of patients. Test results can be used to devise physical therapy programs or other rehabilitative procedures and to document recovery. For example, sequential tests in patients recovering from vestibular injury can graphically demonstrate the patients' ability or inability to compensate centrally for the injury. This information

is valuable to both physicians and patients in assessing progress and directing the decision for further therapy.

In summary, moving platform posturography is rapidly becoming a useful adjunct to conventional neuro-otologic tests in evaluating dizziness and imbalance. In addition to assessing a patient's ability to use vestibular information to control balance, this test provides a multifaceted assessment of motor responses to challenges to balance. It thus provides an important evaluation of a patient's functional balance capacity that can be used to direct rehabilitative programs.

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Improved Diagnosis of Acoustic Neuroma With Auditory Brain-Stem Evoked Responses and Gadolinium-Enhanced MRI

THE most frequent reason for a clinical suspicion of acoustic neuroma is a unilateral or asymmetric sensorineural hearing loss, although patients may present with persistent vertigo or other neurologic symptoms. As only about 5% of patients undergoing evaluation for an acoustic neuroma will ultimately be found to have a tumor, an efficient and economic diagnostic tree is essential. Following a standard audiometric evaluation, which identifies patients "at risk," auditory brain-stem evoked responses (ABRs) are obtained when there is sufficient residual high-frequency hearing. The ABR is a computer-averaged recording of the changes induced in the electroencephalogram due to sound stimulation. A series of peaks that correspond to different levels in the auditory central nervous system is generated. The results of the ABR are abnormal in more than 95% of patients with proven acoustic tumors. When the latency of the most prominent wave (V) is symmetric and within normal limits, an acoustic neuroma is improbable. The rare false-negative findings generally occur in patients whose acoustic tumors have arisen in the cerebellopontine angle, rather than within the internal auditory canal. False-positive ABR studies are common and indicate the need for an imaging study.

The definitive diagnosis of acoustic neuroma requires an anatomic visualization of the cerebellopontine angle

and the internal auditory canal. Contrast-enhanced computed tomographic (CT) scanning reliably visualizes larger tumors but detects less than 50% of tumors that are less than 2 cm in diameter. As the ability to preserve the function of the auditory and facial nerves is highly dependent on tumor size, detecting tumors when they are small is a primary goal in acoustic tumor diagnosis. Recently magnetic resonance imaging (MRI) has become the diagnostic imaging technique of choice in the evaluation of acoustic neuromas, and it has numerous advantages over CT. It provides a noninvasive means of detecting very small tumors that previously would have required gas-contrast CT. False-negative studies appear to be exceedingly rare when a proper slice thickness and imaging technique are used. A few false-positive MRIs have been noted, especially in patients with large internal auditory canals. Within a wide canal that is partially compartmentalized by arachnoid webs, restricted cerebrospinal fluid circulation may lead to an increased protein concentration in the trapped fluid. This returns a bright signal on T2-weighted images. Until recently, adjudicating such equivocal MRI results required gas-contrast CT scans. The introduction of the MRI contrast agent, gadolinium DTPA, however, has rendered this unnecessary. This paramagnetic metal ion, which was recently approved by the Food and Drug Administration, induces a notable increase in the signal intensity of an acoustic neuroma. It has been used in more than 10,000 patients worldwide without significant morbidity. Aside from reducing the incidence of false-positive studies, gadolinium contrast MRI has, in our series, revealed several small tumors that were entirely inapparent on nonenhanced MRI scans. Gadolinium-enhanced MRI also appears to be useful in cases of possible recurrence where differentiating tumor from scar tissue or implanted muscle plug may be difficult using other techniques.

Magnetic resonance imaging also displays surgically important information that was not available on earlier studies. On MRI, the lateral extent of tumor penetration in the internal auditory canal can be evaluated. This both assists the surgeon in planning the operative route (translabyrinthine, retrosigmoid, or middle fossa) and in differentiating an acoustic neuroma from other cerebellopontine angle neoplasms such as meningiomas, which usually do not possess an intracanalicular component. Another advantage of MRI is its ability to visualize intrinsic brain-stem disease such as multiple sclerosis that may mimic the clinical presentation of an acoustic neuroma. In summary, MRI with gadolinium contrast has virtually rendered obsolete all other imaging methods used in diagnosing and characterizing acoustic neuroma. Computed tomography is reserved for those patients known to have metallic implants (MRI hazardous) and in those 5% to 10% of patients who, because of claustrophobia, are unable to tolerate insertion into the magnet.

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Implantable Hearing Aids

ONE of the new and exciting advances in otolaryngology and head and neck surgery is the development of hearing devices designed to be implanted in the ear of patients with mixed or conductive hearing loss. These devices have some similarities to cochlear implants used for profound hearing loss, but the indications are different.

At this time two basic types exist. In one type a magnet-containing bone screw is inserted into the mastoid bone behind the ear. A modified hearing aid containing a microphone, amplifier, battery, and an output coil is worn externally with the coil lying over the implanted magnet. Sound amplified by the hearing aid goes to the coil, which energizes the magnet to vibrate the skull so that the patient hears by bone conduction. The ear canal is left open, avoiding problems of drainage and recurrent infection with a tight-fitting ear mold. Sound quality is exceptionally good. This device appears to be an ideal solution for patients with bilateral canal atresia and inoperable conductive hearing loss.

In the other type, which is still in the experimental stage, a small magnet is placed in the middle ear on the stapes at the time of the middle ear operation. The vibrating element may be contained in a middle ear prosthesis and is externally energized using electromagnetic induction through an external hearing aid with coil. In this version the ossicles are directly vibrated rather than the mastoid bone, a much more efficient system. If the operation fails to totally correct the hearing loss, the implant component can be used to produce amplification. Again, the ear canal is open, minimizing the problems of a tight ear mold. In the simplest version, a magnet is encapsulated in a middle ear prosthesis so that it can be energized by an external coil to vibrate the ossicles. The sound is particularly clear and preferred compared with the sound of conventional hearing aids. Whereas this type of device is still experimental, it is expected to be available soon. The magnetic bone screw is available and is being used for the treatment of certain types of conductive and mixed hearing loss. In the future it may well be possible that these implant instruments will also be used for neurosensory loss because of the improved sound clarity they provide.

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Conserving Hearing in Acoustic Tumor Operations

OF the 2,500 patients with acoustic tumors removed at the Otologic Medical Group, Los Angeles, only 5% were candidates for hearing preservation operations. Unfortunately, the tumor is usually too large at diagnosis for this procedure. In selected cases, however, hearing conservation may be possible using the middle fossa or retrosigmoid approach.

The two most important factors to be considered are the size of the tumor and the level of preoperative hearing. Secondary factors are the preoperative results of brain-stem evoked response audiometry (BERA) and electronystagmography (ENG).

The limit of the tumor size for the middle fossa approach is 1.5 cm and for the retrosigmoid approach is 1.5 to 2 cm. We also prefer patients with good preoperative hearing as candidates for hearing preservation operations. Our guidelines are a speech reception threshold of at least 30 dB and a speech discrimination of 70%.

In our series of 106 patients with removal of middle fossa acoustic tumors, patients with tumors arising from the superior vestibular nerve had a better hearing outcome than those with tumors from the inferior vestibular nerve. This may reflect a greater involvement of the cochlear nerve or cochlear blood supply by tumors developing in the inferior compartment of the internal auditory canal. Preoperative ENG is helpful to predict tumor origin. When such testing showed hypoactive calorics, indicating a superior vestibular nerve tumor, hearing was preserved in 64% of patients. Only 48% of patients had their hearing preserved when the preoperative calorics were normal.

There is a trend toward a better rate of hearing preservation with a relatively normal preoperative results of BERA. For patients with a preoperative intra-aural wave V latency difference of 0.4 milliseconds or less, hearing was preserved in 78%. For greater latency differences, the hearing preservation rate dropped to 58%. With no response on BERA, postoperative measurable

hearing remained in only 50% of patients.

In summary, the ideal candidate for hearing preservation during acoustic tumor removal should have good preoperative hearing, a small tumor, near-normal preoperative results on BERA, and hypoactive calorics on preoperative ENG. The needs of the patient should also be considered, however, and these criteria should be tailored to each patient.

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Botulinum Toxin for Treatment of Spastic Dysphonia

SPASTIC dysphonia is a voice disorder of unclear etiology yet clinically distinguishable by strained, staccato, effortful speech with voice arrests. The vocal abnormality results from spasm or hyperadduction of true and false vocal cords. It is believed to be a focal dystonia, similar to essential blepharospasm, yet the underlying pathophysiology is poorly understood. It has been proposed to be a heterogeneous disorder including different subtypes—psychogenic, neurologic, and idiopathic—or part of a generalized neurologic disorder.

Diagnosing spastic dysphonia involves subjectively evaluating a patient's speech. Although videostroboscopy can be helpful in identifying a laryngeal tremor, standard laryngoscopy, acoustic analysis, glottography, and electromyography are often not helpful. A lack of understanding of the pathophysiology of this disorder has resulted in a myriad of treatments including speech therapy, psychotherapy, biofeedback, muscle relaxants, tranquilizers, and anticonvulsant therapy. The results from these types of therapy, however, have been disappointing. In 1976 recurrent laryngeal nerve section was introduced, which has been the single most effective treatment of refractory spastic dysphonia. The initial results were excellent, but recent long-term reports have found the results to be temporary with a return of symptoms despite unilateral vocal cord paralysis.

Botulinum toxin has been used to temporarily paralyze selected muscle groups to relieve spasm in such conditions as blepharospasm, torticollis, and, more recently, spastic dysphonia. Botulinum toxin A is one of the neurotoxins produced by *Clostridium botulinum*. It interferes with presynaptic release of acetylcholine from the nerve ending, thereby functionally denervating muscle fibers for weeks to months. Chemical denervation of the vocalis-thyroarytenoid muscle is accomplished by percutaneous localization of the muscle using a hollow

electromyographic electrode followed by the administration of a small amount (0.1 to 0.3 ml) of toxin. Initially patients may experience hoarseness and aspiration that subsides in 36 to 48 hours, and increased fluency ensues. Vocal fluency should continue for three to six months, after which the injections can be repeated. In contrast to surgical treatment, both vocal cords can safely be treated eliminating failure due to the functioning cord. Although systemic effects appear subclinical at the present dosage, the long-term effects of the toxin in the larynx are unknown. Studies show that many patients feel the effect of the toxin to be preferable to other pharmacologic therapy. Most patients return for reinjection before their symptoms return. Further study is necessary, but it appears that botulinum toxin is an important new treatment option for patients with debilitating spastic dysphonia.

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Craniofacial Resection for Cancer

IN the past, patients with advanced paranasal sinus neoplasms involving the anterior skull base had a dismal prognosis, and the lesions were generally considered unresectable. In the 1950s, extensive procedures were developed to remove these tumors, yet the outcome of surgical treatment was nearly as bleak as from the tumor, with most patients suffering significant morbidity. Now there is new hope for these patients with the current methods of surgical resection.

There are several reasons for the increased acceptance and success of craniofacial resection. Previously unresectable lesions are now surgically approachable, thanks to new technology and improved surgical techniques. With the progress of computed tomography and magnetic resonance imaging, lesions may be diagnosed while they are smaller and more resectable. Precise anatomic localization has permitted a better selection of surgical candidates and more detailed preoperative planning. Perioperative morbidity and mortality have been substantially decreased to acceptable levels (10% to 15% and less than 5%, respectively) with recent advances in intraoperative and postoperative monitoring techniques. Innovations in reconstruction techniques have allowed improved rehabilitation and reduced the risk of cerebrospinal fluid leaks and other complications. It is important for practitioners to be aware that such a procedure is now available to counsel patients appropriately.

Indications for craniofacial resection include malig-

nant tumors arising from the nasal cavity, maxillary antrum, ethmoid-sphenoid complex, or orbit and extending to or through the cribriform plate. Investigators have found that even patients with some intracranial invasion often do well with this operation. Most candidates for craniofacial resection have already failed other forms of therapy, such as more limited surgical procedures or irradiation or both. Tumor types most commonly include squamous carcinoma, adenocarcinoma, esthesioneuroblastoma (olfactory neuroblastoma), and sarcoma. The best local control is achieved in well-differentiated squamous carcinoma and adenocarcinomas.

In this surgical approach, wide access is gained to the complex structures of the anterior skull base by a coronal flap and frontal craniotomy in combination with a facial incision. The cribriform plate and adjacent dura are removed en bloc with the ethmoid sinuses, nasal contents, and other involved structures such as the orbit or maxilla. The dura is repaired with fascia, the floor of the cranial fossa is reconstructed with a pericranial flap, and the nasal portion of the defect is lined with a skin graft. The cosmetic result is excellent. This is an oncologically sound en bloc procedure, and several series have now shown at least a three- to five-year disease-free survival in about half of these previously "incurable" patients.

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Intraoperative Facial and Auditory Nerve Monitoring

THE general principles underlying intraoperative monitoring of patients have been well established in anesthesiology: to provide an ongoing record of some physiologic function, to alert the surgeon when an undesirable change in that function occurs, and to provide feedback as to the efficacy of corrective measures that were taken. Through the development of specialized electrophysiologic monitoring techniques, preserving auditory and facial nerve function during surgical treatment in the posterior cranial fossa is becoming more the standard than the hoped-for exception of previous years. Moreover, these goals can be achieved noninvasively and without significantly delaying the operation.

Monitoring of the facial nerve is useful in the following: identifying surgical trauma to the nerve early, enabling the immediate notification of the surgeon; distinguishing facial nerve from adjacent nerves or from surrounding tissue or tumor; facilitating tumor removal

by electrically mapping regions of the tumor for the presence of facial nerve; confirming nerve stimulatability following tumor removal in order to predict postoperative facial nerve function; and identifying the site and degree of neural degeneration in patients explored for possible facial nerve neoplasm or decompression of acute facial paralysis. Monitoring of facial function is carried out using standard electromyographic recording techniques with needle electrodes placed in the periorbital and perioral musculature. Facial nerve activity following stimulation, either unintentional as the result of trauma, or intentional using a hand-held stimulator, is monitored visually on a screen or routed to an audio amplifier for immediate feedback to the surgeon. The predictive efficiency for facial nerve function a year after the operation has been reported to be as high as 88%.

Monitoring auditory nerve integrity is accomplished using standard techniques for evoking the auditory brain-stem response, during surgical treatment of the posterior fossa such as acoustic tumor removal, vestibular nerve sections, microvascular decompressions of adjacent cranial nerves, and removal of other vascular or neoplastic lesions in proximity to the auditory nerve. As with other forms of monitoring, its value lies in providing immediate notification of significant changes in response

amplitude and latency associated with surgical manipulation of the nerve or brain stem. Such changes, if uncorrected, may precede complete degeneration of the response, leading to profound, irreversible hearing loss postoperatively. If the response remains stable throughout the operation, the postoperative auditory status will be essentially unchanged from preoperative. Postoperative worsening of hearing is predicted with approximately 80% efficiency when persistent latency delays occur. Intraoperative monitoring of auditory brain-stem evoked responses provides the most direct means of assuring the preservation of auditory function during posterior fossa procedures.

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The Ethos of Public Health

ARTHUR J. VISELTEAR, PH.D., M.P.H.

THIS is a grand day: a great University: a happy occasion!

We are gathered to celebrate your commencement, a treasured moment for you, a joyous occasion for those whom you cherish, and a special privilege for me as I now share this experience with you.

On this stage, in this theatre, have been performed some of the great dramatic works of our time.¹ The dramatists are well known to us; their words of truth ring in our ears and excite and haunt us; their characters live in our hearts and mind. Through what we see and hear on this stage, we experience catharsis, purification, spiritual renewal. We are moved, shaken, touched deeply, informed, made wiser.

My task this afternoon is to find just the right combination of words and sentiments to share with you which will have similar significance and which also will ring true. My words certainly will not be as immortal as those which have been spoken by the characters who have appeared on this stage, but, I hope, what I share with you today will be no less meaningful.

My message is really rather simple and comes in the form of an admonishment: Do not forget the public health ethos; do not forget public health's essential and distinguishing character; do not forget public health's tone and guiding beliefs.

What, then, is the public health ethos? It is, I trust, something which brought you to Yale in the first place.

When the first chairman of this school, C.-E.A. Winslow, was a high school student in Boston, he sought admission to the Institute of Technology, known commonly as "Boston Tech," now known, of course as M.I.T. Winslow was interviewed by William Thompson Sedgwick, then the leading sanitary scientists of his day and chairman and professor of the newly established

department of biology. Sedgwick showed Winslow the laboratories and lecture halls, discussed with him the great significance of the public health crusade, and told Winslow of the opportunities available for those wishing to enter the field of public health. After their discussion, Sedgwick looked over his spectacles, smoothed down his walrus mustache, and said: "Well Winslow, I think you can be a useful man."²

When recounting this story in 1942, at the occasion of his receipt of the Sedgwick Award, the highest honor bestowed by the American Public Health Association, Winslow reminded those present that Sedgwick had said only that he could be useful: not wealthy, not even happy, but someone who would contribute, who would add to the sum total of the common good.

And this became Winslow's and the Yale School's fundamental credo: to do good, to be useful, to be civilly constructive.

Can you imagine a more useful profession than public health; a profession which has such an incredible array of critically important responsibilities; a profession which has been programmed to do so much good? There is none.

When Winslow entered the profession at the turn of the century, he had already understood that society was undergoing changes that needed to be addressed by a new, a more dynamic public health. Water had been made potable, food and drugs unadulterated, children immunized, women and laborers protected, factories made safe, and homes made habitable, but public health had simply not lived up to its full potential.

No matter how well the public health profession managed its affairs, personal health services — the way we in this country organized, administered and financed medical care — remained incoherent and desultory. Sickness was found to be inversely proportional to income; chronic disease remained uncontrolled; immunization rates were low; medical care had become costly, creating a financial barrier between physicians and patients; and medical services were not preventive but

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alleviation after the event.

Public health soon became more than an engineering or sanitary science; more than a clinical or medical science. Instead, public health became a social science, one which would lead to an emergent profession, pushing its boundaries ever outward — extending from environmental hazards to tuberculosis and venereal disease control, from maternal and infant welfare to the prevention of cancer, from immunization to national health insurance.³

Public health soon spoke for the weak, disenfranchised and sickly; for societal coherence; for programmatic approaches to national issues; for using national resources to remove economic barriers to good medical care by sharing costs; for fundamental research to determine the etiology of the infectious and chronic diseases; for epidemiologic investigations to discover the physical and social determinants of disease in society.

And while this was going on, where were the physicians? Well, at first, the professions of medicine and public health were closely aligned in these endeavors, for many of our foremost public health educators — including Sedgwick, Rosenau, Welch, Biggs, Winslow, and Emerson — believed that both professions needed each other to fulfill their primary responsibility to protect and maintain health.

It soon became evident, however, that there were fundamental differences between the two professions, differences which would result in there being constructed an impenetrable barrier between medicine and public health. One difference was based on an economic imperative which held that, as the medical profession was concerned primarily with cure and reimbursed on a fee-for-service basis, the public health profession perforce must be regulated entirely to providing those services in which the private physician had no interest; and the second was the rise of the basic sciences, which led to the emergence of the medical specialties and the enthronement of reductionist medicine, upon which the medical schools and the medical profession justified as their primary mission sickness and not health, the patient and not the community, cure and not prevention — all principles which are at variance with the public health ethos.

We come now to a new concern, the rise of the private sector in the health care field. Schools of public health, and this appears true for medical schools as well, are in a state of transition. A society which now finds it convenient to refer to physicians as providers and patients as consumers will not be surprised to learn that more and more of our public health graduates are seeking employment in the private sector. There is certainly much that can be learned in a school of public health that will benefit those students who chose to enter private sector jobs; but how vastly different such employment is from

the positions sought by those who entered the public health profession in the early decades of this century.

Where is the public health, or social, ethos to be found in corporate America? Our job is to educate the next generation of leaders for public health, those who will take their places in the public sector at all levels of government, leaders for the voluntary sector, for international health, for philanthropic foundations, for the community, for the health sciences, for academe. It is for these areas that the profession of public health was established in the first place, and fiscal exigency or crises of faith should not be permitted to change our constituency or modify our historical and fundamental mission, which is to educate the next generation of public health elite: the public health scientists, academic researchers, and executive authority practitioners.

And so the third component of the public health ethos — the guiding principle itself — must be public service, social utility, usefulness, and altruism.

In 1945, Winslow was invited to deliver the commencement address at the Yale School of Medicine. In this address, his Yale valedictory, Winslow told the students that one of his favorite books was H.G. Wells' fantasy, *The Food of the Gods*, in which a youthful giant who has been raised in ignorance of the world about him escapes to London where he stands towering above the frightened crowds. Amazed at their number and activities, the youth cries out in wonder: "What are all you people doing with yourselves? What is it all for and where do I come in?" In his commencement address, Winslow asks the students: "What are you all for anyway?" And his answer — and his message — was a quote from Matthew Arnold's essay "Culture and Anarchy." Arnold wrote:

"...there is of culture another view in which not solely the scientific passion...appears as the ground of it. There is a view in which all the love of our neighbor, the impulse toward action, help, and beneficence, the desire for removing human error, clearing human confusion, and diminishing human misery, the noble aspiration to leave the world better and happier than we found it — motives eminently such as are called social — come in as part of the grounds of culture..."⁴

It was man's duty to strive, to leave the world better and happier than he had found it, to be useful, to advance always with hope and courage: that was the motive for a life of service in the cause of humanity. And it is also what I mean when I implore you not to forget the public health ethos.

Your future — our collective future — has recently been called into doubt. I believe that we shall weather that storm and be stronger for the experience, that we shall not only endure but prevail, and I present you with a series of questions which I ask you to consider as you

leave Yale to enter your life's work.⁵

You have evolved from sanitary scientists and go forth today as graduates of a modern school of public health; can you adapt to our rapidly changing environment and maintain you integrity? You are ambitious; will you let your ambition overwhelm your compassion? You are concerned with the instability of government's commitment to social justice; will you help determine government's proper role in our complex society as the pendulum swings away from desperately needed social programs to sterile efficiency? You shall be working in a crazy quilt system which relies on all categories of health professionals, including the physicians; will you be able to work collaboratively and productively with this new amalgam to assure societal health and well-being? You are now organizational, evaluative, numerical, laboratory, and policy wizards; will you be able to utilize your special talents and creative energies and look beyond your narrow spheres of expertise to address societal concerns? The world is changing rapidly; will you do your share to influence the future? Economic reality is closing in upon you; will you remember and hold dear

the public health ethos?

Members of the Class of 1989: You have fulfilled the responsibilities that the Yale School of Epidemiology and Public Health have imposed upon you; are you willing to establish your own place in the flow of events which leads you to this moment and beyond?

All of us who are here today, who love and embrace you and now let you go, have a stake in how you answer these questions.

We wish you well; good luck and Godspeed!

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5. The statements and questions which follow have been adapted and modified from Henry Steele Commager, *The American Mind: An Interpretation of American Thought and Character Since the 1880's*, New Haven, 1959, pp. 441-3.

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An Experience in Social Medicine: The Jardin Mafalda in Bogota, Columbia

GREGORY ARMSTRONG

THE Barrio La Cordillera sits on a hill above the eight-thousand-foot plateau, flanking the southern extreme of Bogota, Columbia. It seems to provide a natural dam against the expanding human populace that engulfs Bogota. On a clear day one sees from it the sprawl of Bogota, from the eastern mountains to the northern suburbs and back to the slums and factories of the South. The vantage point provides a more poignant view of life in the South than the descriptions I had read while sitting in my bedroom in the suburbs.

On this hill there is no shade from the sun, no breaks to stop the omnipresent wind from the North. This barrio is a new "barrio de invasion," filling with the incessant migration from Columbia's countryside. There are no paved roads or street lamps. Cardboard and corrugated metal shacks lead up to the mountain's crest; open sewers and mud walkways follow back down, walkways in which the children play.

On this day a woman named Esneda, a few of her coworkers, and myself have come to this Barrio to speak with the inhabitants about possibly building a day-care center (*jardin infantil*) like the one their group founded in another community, San Pablo. A large crowd sits patiently by at a potential site. Where life is so impoverished, an event such as this always attracts a crowd.

We've brought with us one bag of rice, and another filled with animal viscera. Both are to be cooked at the meeting and eaten in celebration. Both are gifts from the Jardin staff, symbols of solidarity with the people of this Barrio. Behind the gathering crowd a cooking fire is lit.

Esneda and a local call the meeting to order, explaining that this session will be devoted to planning the center. They ask that every adult present sign a sheet of paper being passed around. As discussion begins, a man standing conspicuously with three others steps forward and butts in, "And where do you propose to build this center?"

The representative falls silent. For a moment the

crowd looks away in quiet resignation; this interruption was not unexpected. But Esneda moves forward: "We're going to build it here!"

"Do you have the money to buy the lot?"

"We don't need to buy the lot; it belongs to the community!"

The man chuckles; his friends smile. "Of course," he says, "that's why you have to buy it from the Junta Comunal."

The crowd is still passive, but its eyes are on Esneda. "You don't represent these people. This land belongs to them, and if they need to build a day-care center here, nothing can stop them."

"My dear lady, we have nothing against such a center, but if you insist on stealing the land, we will have to send the police to remove you."

"This land doesn't belong to you! The money you collect is supposed to be used for community projects, but where does it go? Drink! You and your friends use it for drink."

"We suggest you break up this meeting now. With no lot, you have no place to build the center. If you build it here, the police will tear it down." He turns, and leads his group away.

The silent stares of the crowd show that this threat is not to be ignored. "What do we do now?" the representative asks Esneda.

"We build it here! Look, all of you: they have no right to tell you what to do with this land. If you need it then use it!"

Though still intimidated, the people agree to look into funding, and to send two representatives to learn basic accounting. The gathering closes with the food. The children are served first; everyone receives a piece of the meat.

As we descend the mountain, Esneda points to a group of workers playing tejos (a game) beside an unfinished public-works project. "Look at that!"

We return to Barrio San Pablo. A message arrives a

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week later from La Cordillera saying that the Junta Comunal has decided to let the center be built on their lot. It is a small, unexpected victory.

II

I went to Columbia for the summer of 1986, between the first and second years of medical school, to improve my Spanish skills and to gain insight about poverty in urban Latin America. My exposure to a very poor Barrio altered conceptions based on my experiences with poverty in the United States and Africa.

I chose the program in Bogota for its cultural immersion. I hoped that the experience would provide a chance to see how the poor majority lives in this corner of the world. My hopes were dashed when my host family collected me in their Ford LTD and drove me to their two-car-garage house in the suburbs.

The next morning they drove me around the city. On an eastern hill one of the sons explained: "We can see all of the North of Bogota from here." He pointed out a new shopping mall. "The mountain to our left blocks our view of the South, but there isn't much to see there anyway." Later, as we were driving past the old colonial section, he pointed to a group of rag-clad adolescents loitering in the street, who stared at us as we passed. "Be careful not to wander South of here," he warned, "Es muy peligroso!"

But like an adolescent myself, I took this warning as a challenge. The forbidden, dangerous and unseen part of the city intrigued and beckoned. Yet the warning could not be casually dismissed. To see the South, I would have to learn the rules. I began to search for volunteer work to occupy my unscheduled afternoons. I looked for a project in international health that would fulfill my curiosity about the South. This combination was hard to find.

My search had begun months earlier with letters of inquiry to many international health organizations. Most had not responded, and the others had only sent job applications. I had concluded that it would be easier to find work on-site. At the fortified American embassy, after being shunted from office to office, I was finally told by a U.S.-A.I.D. officer that they knew nothing about any medical projects. Next I contacted an American missionary, who stated that in his entire career in Bogota, his sole visit to the South had been cut short when stone-throwing youths chased him out of their Barrio. He couldn't understand how this happened to someone wearing a clerical collar. At last at the French embassy I was directed to the National Office of Indians, a nonprofit group that coordinates Columbia's various Indian organizations. This office introduced me to Martine, a French nurse working at the Jardin Mafalda, a daycare center. Her account of the place made me excited about the possibility of working there.

III

The Barrio San Pablo is situated on Bogota's eastern mountain range in the southern part of the city. It was

born many years ago as a "barrio de invasion," similar to the nearby Barrio La Cordillera. It has matured and now exhibits trappings of permanence: paved roads, electricity, and running water. Poverty remains all too evident. Most houses consist of unfinished brick pierced by glassless windows, with patchwork roofs of rusted, corrugated metal. The entire Barrio is ensnarled in a hopeless tangle of thin, colored electrical wires that are constantly overloaded with current. The lights often dim as a result. Beneath this net run hundreds of children dressed in rags, playing with whatever they find that passes for toys. At night, street vendors emerge to set up tables beneath the streetlamps and to sell what little they can as they pass the evening chatting with friends.

The Jardin Mafalda was founded in this Barrio. The women who leave their children at the Jardin every morning now struggle to balance survival with their obligations to their children. Most are single mothers, their husbands or lovers having departed. Each morning they rise before the sun and leave San Pablo on a bus for the North, where they work as domestics for families like the one I was staying with. They earn 30 to 50 dollars a month. Before the Jardin was established, many working women would lock their young children inside their one-room dwelling, and there they stayed until the mother returned in the evening and let them out. As the kids grew, the pattern would change: now the mother would lock them out of the house when she left for work, leaving them to cope in the street.

This situation still prevails in most of Bogota, but a woman named Esneda, with a few friends, changed this for San Pablo by founding the Jardin Mafalda in 1982.

Esneda's main concern early in life was survival. She never knew her parents or her birth year (she thinks it was 1940). She was an orphan in the South of Bogota from early childhood. By about age seven she had begun working full-time at a church, helping to cook and clean. This left neither money nor time for school, so she did not learn to read. She married in early adolescence and had borne six children before her 22nd "birthday." Her poverty, even before her husband left, precluded staying home to care for the children. She found employment in the North, doing wash for wealthy families and caring for their infants while her own were watched by their siblings back in San Pablo. None of her sons or daughters attended school beyond fifth grade.

At age 24 Esneda became involved in political activity. In the evenings, after work and after feeding her children, she would attend political meetings, where she finally learned to read. For 10 years she posted signs, distributed literature, and talked with people in the Barrios. She grew disillusioned with her party. "They betrayed us," she now believes. "They spoke very pretty, but never did anything." Ironically, soon after she left the group, her prior association led to arrest. A three-month incarceration, during which she was interrogated—she will not say more—left her devastated for years.

By 1980 she was sufficiently recovered to work at an orphanage. Her new focus was "to do something for the children." Then an incident in the Barrio, in which a child was trapped in his house for four days after his mother's arrest on drug charges, appalled her. She saw that she now possessed skills to empower her calling.

Drawing on organizational skills she had acquired, Esneda began holding community meetings to establish a *jardin infantil* for the Barrio's children. Motivating the skeptical citizenry was difficult. "She's crazy," people would say. "Where will we put it? Where will we get the money?" Although many people might attend a meeting, there was always in-fighting, and people would storm out. But a group of four women, headed by Esneda, persisted. They surveyed the Barrio to determine detailed need, talked with other institutions about funding, and educated mothers about *jardins*.

On 26 January, 1982, the Jardin Mafalda opened in Esneda's two-room house. Thirty-four children came on the first day, and two unpaid women cared for them. The enrollment grew quickly to 80, and a new staff member was hired. Gradually, the Jardin began to receive external funding from the orphanage where Esneda had worked, foreign embassies, and international aid organizations. In 1983 the Swiss embassy donated the cost of a permanent brick building.

IV

Every morning the women arrive early to prepare for the 150 children they now serve. Each woman has one group of kids that she watches. For eleven hours each day she leads them out to play, sees that they eat a full lunch and take an afternoon nap, cleans up after them, praises them, and disciplines as needed. Having known most from birth, she is aware of the problems and concerns of each. When the mothers return from work and claim their children, they chat with the staff about their families.

From its inception, the Jardin was staffed and managed entirely by the Barrio. Much later an outsider, Martine, entered to help set up a much-needed child health program. This program was to involve the Columbian staff in every aspect so that they could continue it independently after Martine's departure.

The health program had begun four months before I came. My simple task was to implement a medical record project that Martine had planned but had lacked means to enact. The health cards would display growth charts and provide a permanent record of each child's immunizations and illnesses. I also assisted Martine daily with treatment of children who had common medical problems such as ear infections and diarrhea. In time I began to teach some of the health classes which Martine had begun for the local women.

My work was mostly routine: weighing and measuring children, filling in health cards, adding vinegar drops to infected external ear canals, cleaning cuts and scraped

elbows. Yet this repetitive work proved rewarding. It offered me the opportunity to work side by side with people I would not otherwise have met. The relationships I built there were the closest I developed during my time in Columbia.

On one occasion things were far from routine: I almost had to deliver a child with only the help of a textbook for village health workers entitled *Donde No Hay Doctor* (*Where There is No Doctor*).

I knew something was wrong when I arrived at the Jardin early that afternoon and was greeted by a staff member who asked, "Greg, you're a doctor, aren't you?" Upstairs a woman lay on a table in full labor, very frightened. Since Martine was away and was not expected home for some time, the responsibility of delivery had fallen to me, who was suddenly being called "The Doctor." I tried in vain to explain the difference between doctor and medical student. The assembled women insisted that I was more than equal to the task; with a little of their help I would perform a flawless delivery. The truth was, not only had I never delivered a child, but I had not even studied the subject and had only witnessed birth in a high school biology movie ten years earlier. My words were enthusiastically ignored.

I knew that what they were saying was largely correct: birth is usually a natural process, and in a pinch even a medical student with no practical experience can catch a baby. At the same time, I was aware of many potential complications which would require a midwife or physician. Therefore, when asked "What should we do?" the answer was, "Take her to the hospital!"

Naturally, the solution was not that easy. The expectant mother knew from experience that the hospital would not admit her if she had not participated in a prenatal care program, a sequence precluded by her having worked full-time until that very day.

At this point Martine returned. She agreed that we were unqualified to deliver the baby. We sent for a taxi and gathered a small group to accompany the woman, giving them enough fare to try several hospitals if necessary.

An hour and a half later we felt sure that they had gained admission. Martine left to finish her work in town, and I resumed my tasks.

By 4:30 p.m. I had finished my work and was about to leave. The taxi reappeared with the pregnant woman and her entourage. Once again, I was in deep water.

"Greg, we went to five hospitals! And none would accept her because of the rule about prenatal checkups! What do we do now?"

We decided to find a midwife, but as I then discovered, none was available in San Pablo. The Barrio was in an awkward and all-too-common transition between displacement of its traditional (if primitive) health system and the arrival of Western-oriented medicine. The laws forbidding midwifery had undoubtedly been established

with the most altruistic of motives. Similarly, the rule excluding this woman from the delivery room had certainly been enacted to encourage prenatal care. These two regulations might have been expected to improve the quality of health care, but in fact together they prevented any form of health care for many individuals.

The next few hours were tense. At last we found an old woman who, although never trained in midwifery, had at least attended several births and felt more confident than I. A crowd of women, all voicing encouragement, surrounded the table on which the expectant mother was having ever more frequent contractions. I stood with one hand holding the patient's, the other holding *Donde No Hay Doctor*, from which I kept reading the chapter for midwives, studying over and over the sections on obstetrical complications while at the same time ordering everything in sight to be boiled.

At one point, one of the women brought Martine's sphygmomanometer to me, telling me to take the woman's pressure. Although I knew how to do so, I had not the faintest idea what to do with the reading. What to do if it was high? Or low? Nonetheless, I reasoned that the performance of this test would be therapeutic. I was right: her pressure was 130/80, and when I assured her that it was perfectly normal, she sighed, relaxed, and thanked me.

At eight o'clock a check of the cervical diameter confirmed full dilation. It seemed that the old woman and I would deliver the child ourselves. At this moment, however, Martine returned and from this point led the obstetrical team. Within half an hour a healthy baby girl was delivered among cheers and congratulations in the crowded office. Although in the end I had played only a small role, I found the new mother pulling me down by my hand, which she had held and squeezed almost continuously through the preceding four hours. Over the noisy room I heard her shouting something I couldn't understand until another woman repeated it: she wanted me to kiss her.

A few minutes later we were all downstairs in the panaderia (a bakery adjoining the Jardin), celebrating with bread and coffee. There were toasts to the first child born in the Jardin Mafalda. Martine and I toasted what we hoped would be the only.

V

The Jardin Mafalda is unique among projects I have seen in the developing world, in that it is entirely a product of the community. It arose from no governmental program, nor from an international development project, but rather from a grassroots movement by people determined and able to overcome a problem in the lives of their children. Except for Martine, the Jardin has been staffed by unrecruited, minimally paid community people.

This project has served to unite the Barrio for other projects. Last year the Jardin built the panaderia next door, both to make bread for the Jardin, and to sell

baked goods for income. Then a group of adolescents installed a library in one of the Jardin's rooms, using books solicited door-to-door from a more affluent neighborhood. They also arranged for education students from the university to teach evening classes to local pupils that could not afford government schools. A group of men set up a carpentry shop where they make furniture for the Jardin and take on odd carpentry jobs. Another man established a sewing shop in conjunction with the Jardin, and now employs several apprentices.

Naturally there have been problems. The Jardin still requires outside financial assistance. For each child, the enrollment fee including meals is 100 pesos (50 cents) a month, which fails to cover operating costs. The remainder comes from such sources as a program of Save the Children. Jealousies among the Jardin's staff have occasionally led to bitter feelings, but these have been ameliorated by institution of uniform pay, shared responsibilities, and periodic meetings to air grievances.

Esmeda remains active, encouraging all with her enthusiasm. She has expanded her effort by helping other communities to establish similar projects.

As I look back at the Barrio San Pablo, one question stands out: how could people living amidst so much poverty and violence retain such a positive view of their lives?

Although the poverty is most evident, violence is no less a fact of everyday life in San Pablo. Street crime is as menacing as anywhere in Bogota, a city known for crime. Political violence, both from the left and the right, is constant. Although I escaped all violence, Martine, who was living in San Pablo, was closer to it: during her first month there, the mother of the family she stayed with was shot and killed by the police. Martine moved to another house shortly thereafter.

How can people who have grown up in these circumstances still retain a sense of community? Even if their gains in outlook and organization are fragile, how can they be optimistic rather than bitter? And how could they have accepted into their community someone like myself, a citizen of Columbia's domineering neighbor to the north?

VI

On an evening towards the end of my stay in the Barrio San Pablo, I leave the Jardin Mafalda and take the short walk downhill to where I catch the buseta (small bus) North. As I wait on the corner, a small group of muchachos (adolescent boys) watches me and talks. Three weeks earlier I would not have left the Jardin unaccompanied at night. But by now these boys recognize me as someone who works at the top of the hill. They will not bother me.

After a few minutes the buseta arrives, already almost full as usual at this hour. We head down the hill, past the cinderblock houses, past the mud alleys. The street is barely wide enough for two cars to pass—buses often

need to drive onto the sidewalk to pass. The dangling electrical wires call to mind a 10-year-old girl I met on my first day at the Jardin. I had been talking with Martine when something bumped into the back of my legs, and on turning around I was surprised to see a trembling little girl, arms outstretched, staring blankly. I was told not to be bothered, that she had been left that way from an electrical accident years earlier. But I could not take my eyes from her as she trembled and seemed to stare through me, through the walls behind me, even through the mountainside behind them.

At the bottom of the hill we leave the Barrio San Pablo, turning right off South 33rd Street and heading north along Avenida Caracas. The sidewalks are crowded with street vendors selling arepas, fried plantanos, and other food.

At South 25th Street a young man boards and speaks to the driver, who then turns off the radio. The young man announces, "Senoras y Senores, half a year ago I left my village near Santa Marta to come to Bogota to find employment. I have still not found any. I am without a place to stay and have nothing to eat. I have decided at last to return to my village and to forget about working here. However, I haven't the 3,000 pesos for bus fare home. Won't you help me? God will be very gracious for your generosity. Thank you for your cooperation."

He takes off his hat and walks down the aisle, collecting small donations. "...Gracias. Mucho gusto. Gracias..."

The driver lets him off around South 10th Street and

he crosses the street to wait for the next buseta. We continue on past the National Police Headquarters where armed guards stand behind walls of sandbags. As we pass the silent skyscrapers on North 19th Street the traffic thickens with cars heading home from the office buildings. We continue past the restaurants, and now a three-lined grass median divides the Avenida.

An hour and 15 minutes after leaving the Jardin I arrive at North 100th, where I continue on foot past the white "Ibeme" (IBM) building with its green lawn, its high fence; and its armed guards; past the "Tres Elefantes" department store, and finally to my lodgings on North 101st, a quiet suburban street lined with two-story houses. Inside I sit down and the maid serves me dinner. The Senora comes downstairs, greets me, and sits down at the table.

"Did you go to the Jardin today?"

"Yes."

"Oh, that's such a nice thing to do! Those people are so poor, and need so much help," she says. "But, you know, you really should try to make it home on time for dinner."

"I'll call next time."

After the meal I go upstairs and greet the rest of the family watching television in the master bedroom. I walk into my bedroom, and without turning on the lights I throw my books on the desk and open the curtain. From my window I can see the lights of another poor Barrio like San Pablo; I wonder to myself: What's going on beneath those lights?

Advertising by Physicians

Physician Opinion: As early as 1977, the AMA began to track physicians' attitudes toward advertising by the medical profession. By including a similar battery of items on the 1988 questionnaire, opinions toward this issue over the entire preceding decade were examined.

Do you feel that physicians should or should not be allowed to advertise their professional background to help consumers decide on a physician? (If opinion expressed) And do you feel strongly about that?

	1977	1988
Should be allowed strongly	6%	18%
Should be allowed	22	29
Should not be allowed	24	11
Should not be allowed strongly	41	35
Unsure	5	7

An interesting pattern emerges over time in physicians' attitudes toward advertising. The plurality in 1988 (35%) still was strongly opposed to physicians advertising professional backgrounds. A plurality holding this view (41%) existed in 1977. However, the balance of opinion has shifted from 65% in 1977 against advertising and 28% for advertising to 46% against advertising and 47% for advertising in 1988.

The demographic differences by age are informative in better understanding this change. In the most recent survey, it was the physician group 56-65 that was most negative toward the concept of advertising professional backgrounds. Young physicians favored this form of advertising, 51% to 43%.

(Continued on page 479)

South Park Inn Medical Student Clinic

WILLIAM T. LYNDERS, M.D.

SOUTH Park Inn is a shelter for the homeless at the edge of Hartford's downtown district. Filled to capacity most of the year, the shelter serves a transient population. The majority of the homeless are without employment, lacking enough money to adequately shelter, clothe, and feed themselves; many have complicated psychiatric, alcohol, or drug abuse histories.

In the fall of 1987 medical students from the University of Connecticut opened a medical clinic at the South Park Inn. The motivation for this initiative was the recognized need for the specialized provision of preventive and acute health care for this unique population. Emergency rooms and resident clinics at local hospitals represented obstacles in many cases for these individuals to gain access to the health care system. A shelter based clinic, it was felt, would offer care in a more sensitive way than was realistically possible by the more traditional routes. Not ignored was the economic benefit that independently funded medical students precepted by volunteer physicians could provide. Furthermore the shelter could serve as an excellent setting for medical education and research in the delivery of health care within the harsh realities of homelessness. Finally, the administrative and clinical responsibilities of running such a clinic would yield experiences not available through the classroom or teaching hospital.

The clinic is open to any shelter resident two evenings each week for approximately two to three hours. Anywhere from six to 14 patients can be seen in a given night. South Park shelters men, women, and children, with average stays of between one and two months. The patient population is broad based: 40% female, 60% male, while 30% are under the age of 16. Nearly half the visits each night involve shelter residents not previously seen in the clinic. The problems encountered include: respiratory 24%, skin 10%, trauma 10%, infestations 10%, gastrointestinal 8%, psychiatric 7%, cardio-

vascular 7%, obstetrical and gynecological 4%, renal or urinary 3%, and other 15%.

Patients requiring more elaborate diagnosis, treatment, or follow-up than is possible at the clinic are referred to outside institutions. The role of the clinic in these cases is that of a patient advocate. Frequently the patient needs assistance with the arrangement of appointments and transportation. A referral form, which serves essentially as a letter of introduction, is given to the patient to take to the referral site. The form is then returned by mail to the clinic and included in the chart. Recently, the clinic has added dental care one evening each week through the efforts of University of Connecticut dental students working with local dentists.

Clinic staff members are all volunteers with the roster composed of more than 20 Connecticut physicians and over 175 medical students. The volunteer physicians come either from the University of Connecticut School of Medicine or from other hospitals and practices in the greater Hartford community. Most physicians have specialty training in internal or family medicine and work approximately one shift every two to three months. Medical students are enrolled at the University of Connecticut School of Medicine and receive elective credit for their participation.

One physician and five medical students staff the clinic each night. Patients are seen by one of two medical teams. Each team is made up of two medical students, one second year and one fourth year (or a third year student who has completed a medical clerkship). The patient is first seen by the medical team who formulate an impression and plan and then present the case to the physician. Acting in a preceptor role, the physician reviews the pertinent history and physical findings with the students and finalizes the management plan. A fifth medical student, usually a first year student, is assigned to patient triage and registration.

The clinic occupies approximately 300 square feet of the basement at the South Park Inn. Two examining rooms are each furnished with examining table, cabinets, wall mounted otoscope, ophthalmoscope, and blood

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pressure cuff. A general use area includes a desk, file cabinets, refrigerator, microscope, medicine cabinet, and portable dental chair that are separated from the examining rooms by a solid partition and curtain. Many of the furnishings were donated by local physicians.

Funds for the clinic are raised entirely by the medical students. Sources include grants, private gifts, corporate and society donations, and benefit events. The principle expenditures are for medications and new equipment purchases. A significant portion of medications are donated by pharmaceutical corporations.

Management of clinic affairs is solely the responsibility of the board of directors in cooperation with the South Park Inn's executive director. The board is composed of medical students elected to a one year term. Directors have specific positions on the board, with the director of planning being the official spokesman for the

clinic and also overseer of the other directors. These include: directors of finance, physician and student volunteers, operations, education and training, information, outcome assessment, and professional services.

On the list of priorities for the homeless food, clothing, and shelter rank above health. Often chronic and acute medical problems are neglected until they become debilitating or intolerable. A shelter based medical clinic offers medical care within a more realistic ordering of priorities. Medical students under physician preceptorship are well suited to provide acute and preventive medical intervention. The clinic serves as an ideal base from which they can act as patient advocates and ensure better provision of medical services. Few models of teaching in medical school incorporate clinical experience with the satisfaction of providing charity care and providing needs that otherwise would not be met.

50 Years Ago

From the *Journal of the Connecticut State Medical Society* August 1939

Prepayment Medical Care

With the passage in the recent session of the General Assembly of House Bill 857, an Act concerning Medical Service corporations, the attention of the profession in the State has been focussed upon prepayment medical care. Prepayment hospital service plans have been in operation in this state for some time. The Public enrolled with eagerness and with the corporations soundly constructed and judiciously operated under the control of the insurance commissioner there has been almost universal satisfaction. The basis for the establishment of prepayment medical care presents a more complex problem. No data has been available to aid in setting up such a plan. Because of this fact and also because of the foresightedness of the Council, our Society has had a committee studying the problem and collecting factual data against the day when it may see fit to engage in or support a plan for prepayment medical care.

The development of methods for organizing payments for medical services has been a subject of much controversy, especially since the depression years beginning in 1930. Organized medicine has been considered by the laity as opposed to such plans for group payment of medical bills, chiefly on the ground that anything of this nature was classed as socialized medicine. The evolution of plans for prepayment of medical services has been rapid, augmented to a great degree by the demands of the public which expected that when hospital service plans were put in operation, medical care would be included.

Prepayment or group payment medical service plans as supported by medical societies fall into two types, those on a unit service basis and those on a cash indemnity basis. The details of operation vary in different parts of the country. Under the unit service plan a schedule of the number of units to be allowed for each service is established and the value of the unit is determined by dividing the amount of money available for medical bills by the number of units of service rendered. Under the cash indemnity plan benefits are paid according to a listing of benefits which limits the amount that can be paid to

the member or on assignment to his physician. The cash indemnity method does not fix the physician's fees but does assist the member to meet his medical bills. The unit service plan appeared first in the states of Washington and Oregon. The California Medical Association has set in operation a state wide plan of the unit service type. The Fulton County (Georgia) Medical Society, the Cincinnati Academy of Medicine and the City of San Francisco have all sponsored unit service plans. Many difficulties have arisen with this type of prepayment medical care. Fees have been reduced in some instances to a point where participating physicians complain that they do not receive sufficient remuneration to enable them to practice good medicine. No allowance is made for differences in ability among physicians of like training. It has been found difficult to determine an income status for the group to be included in the unit service plan.

Voluntary medical expense insurance, as its name implies, is a voluntary insurance plan through which a person may obtain a certain amount of money with which to pay the costs of necessary medical services. The amount of the benefits available depends upon the amount of the premium paid, as in any insurance plan. The House of Delegates of the American Medical Association at its 1938 session put its seal of approval upon cash indemnity plans for medical service.

The Connecticut State Medical Society is now in a position, when opportunity offers, to demonstrate that organized medicine, at least in this State, is not blocking the introduction of medical care at lower rates. No actual contract has yet been drawn but the bill provides for the form of the contract and gives the insurance commissioner authority to refuse approval if he finds the rates are excessive, inadequate or discriminatory. In the words of our Executive Secretary, our Society and its components has a genuine opportunity to meet one of its greatest responsibilities.

—Editorial from *The Connecticut State Medical Journal*, August, 1939.

The Role of the Physician in Home Care

LAWRENCE H. BERNSTEIN, M.D.

THERE is no place like home for providing a familiar, supportive environment for healing. This is a concept embraced by patients but not fully accepted by physicians. Seeing patients at home can be a very rewarding experience for physicians and is very much appreciated by patients. It allows physicians to expand their role as advisors and educators both to their patients and to other health care professionals. Home care also allows patients to be more active participants in the treatment process.

The separation of the practice of medicine from the home setting is a relatively recent phenomenon. During the 19th and early 20th centuries, the home visit was an intrinsic part of physician practice. As medical treatment became more invasive and more technologically bound to services available only in the medical office or hospital, caring for patients in the home was viewed by many in the medical profession as inefficient and inadequate. Gradually, physicians abdicated home care to nursing, and the physician house call became a rare event.

Today, changes in medical technology and a broader understanding of the pathology of disease, disability, and convalescence have expanded the scope and desirability of medically supervised home treatment. The patient's plea to go home sooner or the family's search for an alternative to the nursing home for frail relatives has also stimulated physician interest and involvement in home care and formal home health care services. An estimated

46% of family care practitioners spend part of their week doing home care, and a growing number of physicians are becoming more active in the delivery and management of home health care services.

What then is home care? Does it fit the expectations of our patients? How can we be effective care providers within the context of the home health care system?

A Search for a Meaningful Definition

Home health care is typically defined in terms of the services provided, the kinds of people involved in providing care, the technology and scope of home-based diagnostic and treatment services, or in terms of the Medicare program's specifications. But home care is much more than this.

Home care is caring for patients in the home, and the home care patients are patients who need home care.

Underlying the inherent simplicity of this statement is a conviction that the patient's needs, rather than the patient's ambulatory status, orient and direct the course and setting of care and that caregiving extends beyond the resolution of a medical problem. For physicians as well as patients, home care begins with an understanding of the impact of the patient's medical condition on his or her ability to perform basic activities of daily living. By asking our patients what their illness means to them and what their expectations are for "recovery," we can begin to address the patient's needs in a way that is relevant to that patient.

Consider the diagnosis and treatment of arthritis or urinary incontinence, conditions that are often amenable to home care. By considering what these conditions mean to patients, much can be realized about the direction, intensity, and goal of therapy. A physician might ask an arthritis sufferer, "What sort of trouble are you having with housework, taking a shower, and doing the cooking?" Or, for the patient with mild urinary incontinence: "In addition to my ordering an IVP, what are some of your other concerns about how the incontinence is affecting you?"

The patient with arthritis may respond, "I'm really having trouble cooking, and I feel like I'm going to fall and break my hip each time I climb into the shower." Or,

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for the incontinent patient: "What I really need is to stay dry now so my family doesn't put me in the nursing home and so my wife doesn't have to go up and down the stairs doing the wash all the time."

Both patients want medical solutions to their problems. But they want more than that. They want answers to the problems the disease is creating. By taking the time to ask patients and their families about how they are coping with an illness or disability, the physician learns that incontinence means more than just staying dry; that a gait or balance deficit means more than not falling; and that a disabling condition, like severe arthritis, means more than controlling pain or increasing the movement of affected joints.

The arthritic patient may need physical and occupational therapy at home, a homemaker to help with chores, and assistive devices, such as a transfer bench to enable the patient to safely take a shower without the fear of falling. The patient with nighttime urinary incontinence may benefit from a bedside commode, adult diapers, and perhaps some assistance for his wife. These are all simple solutions—but solutions with dramatic impact on the ability of these patients to live at home and maximize their level of independence.

Incorporating Home Care into Your Practice

If a physician chooses to include home care in his or her practice, what do patients expect? First, home care is as much a matter of style as it is didactic content. Yes, it is necessary to understand the clinical aspects of home treatment, the durable medical equipment (DME) and other modalities that make up home care. This can be learned. Experienced home care nurses, for example, are a valuable source of information on how to care for decubiti in the home without resorting to hospitalization or on what simple maneuvers may help the patient with impaired mobility.

Beyond these techniques, however, there must be a special commitment to the patient. A commitment to look at disease from the patient's perspective and to seek solutions that go beyond traditionally conceived medical intervention and demonstrate a concerned, compassionate, competent response. This does not imply expertise in all areas of home care, but it does require that the physician actively investigate who on the home care team can get the answers. It does not imply that the physician will resolve all problems, but that he or she will consider the social, psychological, and cultural context of a patient's life in devising care plans and will help mobilize the necessary resources to implement those plans.

Home care is different than hospital or office-based practice. The home environment is a place of enormous emotional significance to the patient. It is a place where the physician is the patient's guest in contrast to the patient being a captive in the hospital or a visitor in the doctor's office. Because of the more intimate relationship established with the patient and family in the home

setting, it is inevitable that the physician's whole approach to treatment will be more humane. It is important to note that this is indeed a two-way street. An implicit part of this is a more humane treatment of the doctor by the patient. We become more complete human beings to each other.

More and more doctors are recognizing the advantages of incorporating home care into their practices. Some of these advantages are:

- good public relations and community image for the physician—especially for new practices;
- the enhancement of physician-patient relationships, allowing physicians to express their commitment to the health and well-being of their patients beyond the walls of their office or the hospital;
- the timely identification and management of medical care and other health concerns, reducing the incidence of emergent situations and complications;
- an enhancement of practice efficiency, allowing the physician to draw upon the talents and skills of specially trained home care providers and to respond effectively to the "quicker and sicker" discharge attributed to Medicare's DRG system;
- the opportunity to work with other health care professionals and share knowledge on the resolution of illness and disability;
- the ability to tailor treatment and care plans to a broader spectrum of patient needs by understanding the home environment and the patient's ability to perform activities of daily living in the face of illness and disability;
- the opportunity to educate patients and their families in self care and health promotion activities; and, most basic of all,
- the ability to practice good medicine.

Home care is an *enhancement* of care, not a compromise of care.

Going Beyond the Good Bedside Manner

Clearly, participation in home care requires a strong personal commitment by the physician. Home care can be time intensive. However, including home care in a medical practice is not synonymous with making a lot of house calls. The physician works with other trained professionals to provide care to the patient. The home health agency is responsible for carrying out the physician's orders using agency staff or contract services. The professional staff of the home health agency is responsible for alerting the physician to changes in the patient's condition that may warrant alterations in the care plan.

The availability and willingness of the physician to work as a team player—to consult with the patient, the family, the home health care providers; to develop, review, and update care plans; and to make house calls are often key elements of the ultimate success of a home health care experience. By working with the home health

care provider from the outset to identify resources and to clarify reporting and consultation protocols, the physician will help ensure timely, responsive communication between all caregivers. This will help minimize the administrative impact of home care on an office-based practice.

It is important that the physician understand the scope, modalities, and, to a certain extent, the mechanics of his or her local home care system. This knowledge is necessary in evaluating the appropriateness of a home care strategy and in developing a care plan. It is equally important that the physician embrace a practice style that is team-oriented and responsive to the needs and expectations of patients beyond the resolution of a medical condition.

Patients expect their doctors to do more than astutely diagnose disease and prescribe appropriate medication and treatment. Caring for patients means doing this much for certain. Physicians must be concerned with pathophysiology and disease mechanisms, but we also need to remember that it is the functional implications of a disease that so dramatically affect our patients. By training, we in the medical profession tend to be disease oriented. But being a doctor—a person who is healer, teacher, and patient advocate—means looking at a disease within the broadest context that is relevant to the patient.

Future

What is the future for physicians in home care? All of us will be practicing in an environment characterized

by managed care, tighter financial constraints, and a greater impetus to avoid institutionalization. Physicians' educational needs will be paramount if we are to respond to these changes. If home care is to be part of the mainstream of medicine, it will have to be incorporated into teaching programs, CME courses, and the medical literature.

In addition to learning about home care as a discipline, physicians must learn to access the home health care system. "I know all about it, but how do I get my patient into the system?" The best answer to this question is to contact one of the home care agencies in your community. Most home care agencies are eager for our participation—and business. The legwork of exploring the appropriateness of home care reimbursement, evaluating the home environment, etc, will be done by the agency. The physician focuses on the needs of the patient and manages the treatment process to meet those needs.

For patients, the home has always been the preferred setting for care. By providing medical treatment, nursing, and other supportive services in the home, we allow patients to learn to cope with their conditions in their natural environment. They feel more secure and are able to maximize their independence and lead a fuller life. The practice of home care is more than the cumulative result of utilizing the component parts of home care. The end result is greater than just the sum of its parts.

(Continued from page 474)

Advertising by Physicians

Public Opinion:

For the first time in six years, public attitudes about advertising by physicians were measured in the 1988 survey. The item consisted of four statements with which respondents were asked to agree or disagree. The major finding is that attitudes on most aspects of the issue have not significantly changed. About a 60% majority of American adults continue to believe that advertising by physicians is ethical and proper; about one-third still would think less of their personal physicians if they began to advertise; and almost three out of 10 believe that doctors who advertise do so because they are unsuccessful.

Please tell me if you agree or disagree with the following statements about advertising by doctors.

%Agree	1982	1988
It is ethical and proper for doctors to advertise	64%	60%
Increased advertising will lead to lower doctor's fees	41	30
You would think less of your doctor if he or she began to advertise	33	30
A doctor who advertises is in effect saying he or she isn't very successful	29	26

The one significant shift in attitudes over the six-year period is a loss of faith in the notion that advertising will lead to lower fees. American adults apparently have become more doubtful about the positive effects of a competitive marketplace and are now more likely to expect advertising costs to be passed along to patients. Furthermore, these attitudes are pervasive: few demographic variations were evident in the level of agreement with the statement about the potential for lower fees. The greatest variation occurred geographically, with the lowest percentage of agreement (20%) in the mountain region and the highest in the Southeast (35%).

—The full results of the survey appear in *Physician and Public Attitudes on Health Care Issues* (1989) edition by the AMA.

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A Message from the Medicare Carrier

GERALD I. BLANK, M.D.

MANY of the misunderstandings between physicians and Medicare arise through the mistaken impression that Medicare covers all medical care administered to a Medicare beneficiary. Most physicians understand that the care must be medically necessary and appropriate. Understanding fails, however, when the care is necessary and appropriate but still uncovered.

Some of the areas which will not be paid for are: investigative treatments or procedures, treatments performed with devices or drugs not designated for general use by the FDA, and treatments or procedures specifically excluded by the Medicare program.

One of the best examples of the last category consists of payment for screening procedures: an executive physical, routine chest films or EKG, and survey laboratory tests, to name a few. A recent exception to that rule is payment for mammography which will be covered beginning next year.

The issue with respect to payment for diagnostic screening was recently considered by the Office of Inspector General (OIG). Specifically addressed was Medicare coverage of endoscopic examination of the lower gastrointestinal tract. Travelers/Medicare recently received a report from the Office of Analysis and Inspections, a branch of the OIG. The purpose of this report was to determine the appropriateness of Medicare payments for examinations of the lower gastrointestinal tract; in particular, the extent to which physicians may be billing for cancer screening, a routine procedure which is not reimbursable under Medicare.

A random sample of 294 Medicare-reimbursed claims was selected; records were obtained from 237 of these claims (81%). These were then reviewed by a board certified, practicing gastroenterologist; the findings were as follows:

Thirty procedures were determined not to be covered for Medicare reimbursement because of clear indications in the medical records that the procedures were performed for cancer screening purposes.

Six procedures were not justified since results of previous procedures and/or tests were conclusive in the diagnosis and/or treatment of the patients' condition.

Five procedures were performed on patients who did not have any recent history, laboratory evidence, or clinical symptoms indicating the necessity for the procedure.

Three follow-up surveillance procedures were performed without medical justification six to 12 months prior to the time called for by current practice and general guidelines.

Twenty-one procedures were performed on patients whose medical documentation was insufficient to enable the reviewer to make a determination that the procedure performed was covered. In these cases there were no medical record notes of symptoms, laboratory test results, or medical history to indicate the necessity for performing the examination.

In summary 65 procedures (27.4%) were felt to be inappropriately paid by Medicare. Projecting these findings to the 1.5 million claims paid in 1986 suggests that Medicare paid \$39,249,000 inappropriately.

In addition to the above information the claim forms themselves were examined. The intention was to determine whether the information on or attached to the claim form would justify considering the services covered under Medicare's guidelines in the absence of the actual medical record. The results indicate that 221 of the 237 claims (93%) contained what would seem to be sufficient documentation to presume the endoscopic procedures were covered.

At the conclusion of this study it was recommended that the Medicare carriers provide information to the medical community regarding the limitations of Medicare coverage for such procedures and the medical documentation necessary to support payment.

In addition it was recommended that we give increased attention to these procedures as part of postpayment review; ie, reviewing for appropriateness some of these claims with a view toward recovering those payments found to be in error.

GERALD I. BLANK, M.D., Medical Director, Travelers Medicare, Hartford, CT.



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Animals in Research

AMA COUNCIL ON SCIENTIFIC AFFAIRS

WITHIN this century, spectacular advances have been made in the prevention, diagnosis, and treatment of many diseases. With expansion of our basic knowledge of processes involving biochemistry, physiology, and molecular biology, important new directions in medicine have been taken. Although medicine requires research for the development of new thought, the research process itself is less well understood. The brief glossary herein, which is organized to provide ready access to diseases and/or disciplines, cites some of the most important new discoveries in medicine and their bases. The list is not meant to be exhaustive, and research crucial to certain fields is omitted. Its purpose is to emphasize the research process and to point out the mechanisms by which answers often are obtained. The theme presented within the glossary is the indispensability of animals in research, often because animals and humans suffer from many of the same diseases. In fact, much of biomedical research using animals has resulted in significant benefits in veterinary medicine as well as human medicine.

Since the late 1800s, the American Medical Association has consistently supported the humane use of animals for biomedical research. Research that involves animals is essential to improving the health and well-being of the American people, and the American Medical

Association actively opposes any legislation, regulation, or social action that inappropriately limits such research. Most Americans support the use of animals but want assurance that animals are treated humanely and used only when necessary. Over the years, animal rights activists have exploited this concern for animal welfare and have attempted to impede or stop biomedical research with animals. As a result, some Americans believe that abuse of laboratory animals is common. Recently, the animal rights movement has been making substantial inroads in obtaining philosophic and financial support for legislation and regulatory changes that could compromise the future of biomedical research.

The activities and arguments of animal rights groups present difficult ethical questions. To accept the philosophic and moral viewpoint of the animal rights movement requires a total ban on the use of animals in biomedical research. The consequences of such a step would slow the pace of health-related research and impede new procedures and technologies from reaching clinical medicine. Laws and regulations directed toward improving the conditions under which biomedical experiments that use animals are conducted have had a measurable impact. The American Medical Association supports regulatory policies enacted to protect animals from unnecessary pain or inappropriate use; however, pain and suffering in human beings will occur if policies advocated by animal rights groups are adopted. Therefore, the American Medical Association believes that what must be recognized and weighed in the balance is the cost of such protection and comfort in terms of human health.

The medical accomplishments delineated below were developed by research investigators using animals. The list reveals only a small part of the crucial role animals have played in contributing to major advances in reducing morbidity and mortality for all of society.

Aging

- Amyloidosis has been studied in dog kidneys because there are direct relationships between infections and immunologic disease and the deposition of amyloid. This has served well as an animal model for human amyloidosis.

Members of the Council on Scientific Affairs include the following: George M. Bohigian, MD, St Louis, MO, Chairman; Scott L. Bernstein, Champaign, Ill; Yank D. Coble, Jr, MD, Jacksonville, Fla; E. Harvey Estes, Jr, MD, Durham, NC; Ira R. Freidlander, MD, Minneapolis, Minn; Patricia J. Numann, MD, Syracuse, NY; William C. Scott, MD, Tucson, Ariz, Vice Chairman; Joseph H. Skom, MD, Chicago, Ill; Richard M. Steinhilber, MD, Cleveland, Ohio; Jack P. Strong, MD, New Orleans, La; Henry N. Wagner, Jr, MD, Baltimore, Md; William R. Hendee, PhD, Secretary; William R. McGivney, PhD, Assistant Secretary; and Jerod M. Loeb, PhD, Staff Author.

From the Council on Scientific Affairs, American Medical Association, Chicago, Ill.

This report was presented to the House of Delegates of the American Medical Association at the December 1988 Interim Meeting as an informational report of the Council on Scientific Affairs.

This report is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all of the facts and circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and patterns of practice evolve. This report reflects the views of scientific literature as of November 1988.

- Since elderly dogs exhibit neuritic plaques, one of the pathological changes seen in Alzheimer's disease in humans, dogs serve as animal models for the study of this disease.

- Primate research has identified one of the important pathological features of Alzheimer's disease: the abundance of neuritic plaques or clusters of nerve endings surrounding a core of extracellular amyloid in the cerebral cortex.

- Inbred and randomly bred strains of rats show major, spontaneous, age-related lesions in the kidney and heart as well as in the nervous, skeletal, muscular, vascular, endocrine, and immune systems; thus, they have been used extensively in research on aging.

- Because the immune system in mice declines in functional ability with age in a manner similar to that in humans, the mouse has been used for immunologic studies of aging.

- The impact of diet on biologic mechanisms in aging has been delineated using primate models.

Acquired Immunodeficiency Syndrome

- Currently, chimpanzees are the only primate species capable of being infected with strains of human immunodeficiency virus, although none has yet developed an acquired immunodeficiency syndrome-like disease. This is not surprising since only a small number of chimpanzees have been infected for more than 4 years and the incubation period for acquired immunodeficiency syndrome may extend to 10 years or more in humans. Simian immunodeficiency viruses are closely related morphologically and antigenically to human immunodeficiency virus and other slow viruses. The original simian immunodeficiency virus was isolated from captive rhesus monkeys.

Anesthesia

- With the development of equipment for anesthesia and the maintenance of positive-pressure ventilation, it became possible to perform chest surgery on dogs. Subsequently, this procedure was adapted to use in humans. In the late 1930s, the first patient with lung cancer had a lung removed and survived the operation. The patient lived another 40 years and is a classic case in American surgery.

- The dog was one of the primary research subjects used in the development of hypothermia as a means of temporarily reducing brain metabolism and preventing shock and brain damage during prolonged neurosurgery.

Autoimmune Diseases

- Induced autoimmune disease, particularly allergic encephalomyelitis, thyroiditis, arthritis, myasthenia gravis, and renal disease, has been studied extensively in rats.

Basic Genetics

- Many aspects of the structure and function of the histocompatibility complex were delineated using rats.

- Comparative gene mapping between humans and experimental mammals has made it possible to identify with certainty animal models of many human genetic diseases.

- Virtually all basic information on genetic mechanisms obtained from the study of simpler organisms, such as yeast or *Drosophila*, has been tested for relevance to the biology of humans by first analyzing mechanisms in mice because many genetic and physiological traits are similar in mice and humans. Understanding of mRNA transcription, production of a polypeptide chain, folding of a polypeptide chain, glycosylation, assembly of the immunoglobulin molecule, cell secretion, immunoglobulin transport, and action at target sites have been made possible only through the availability of animal models.

Behavior

- Behavioral characteristics that are influenced by heredity, such as aggression, learning, shyness, capacity to adapt to the environment, and temperamental stability, have been studied in dogs. Behavioral patterns have been selected and preserved in many dog breeds by careful breeding. Relationships between behavior and cardiac activity (particularly the association of arrhythmias with fear and stress), anorexia nervosa developing from isolation or psychological trauma associated with food, and the hormonal control of behavior, learning, and dominance have been accomplished using the dog as a behavioral research subject.

- Evidence that the normal development of visually guided reaching behaviors results from self-produced movement and the feedback associated with it was first obtained with cats.

- The biologic commonality in psychological functions in rats and men resolved the man-animal difference controversy and justified using animal models as a general approach in biomedical research.

- Rats were used to help prove mendelian inheritance in animals.

- The broad fields of educational and psychological measurement were developed using rats.

- Research on depression in young primates identified short- and long-term physiological changes in heart rate, immune response, sleep pattern, activation of the adrenocortical system, and neurotransmitter synthesis, uptake, and metabolism in the brain. These effects resemble the disordered physiology of human affective disorders.

- Studies on young monkeys have indicated that genetic factors and predispositions contribute to the development of behavioral problems such as chronic anxiety.

- Research on communicative abilities in primates has provided a practical benefit to human society: a new approach has been developed for teaching language to children who, because of severe mental retardation, cannot learn a language in the same way as normal children.

- Studies with cats, primates, and humans who had undergone commissurotomy for intractable epilepsy challenged the view that the right hemisphere of the brain is subordinate to a supposedly more highly evolved and intellectual left hemisphere; this work led to the observation that left-right hemisphere cognitive differences in man are subtle and qualitative.

- The behavioral effects identified after removal of

precise areas of the brain in rats resulted in the development of many innovative neurosurgical procedures in humans.

- Experiments in rats provided the first clue that obesity might shorten the life span and that weight patterns might be determined by early nutrition.
- The mouse has been one of the principal research animals used to expand our understanding of genetically related aspects of mammalian behavior. The availability of inbred strains, mutants, congenics, and recombinant inbreds with differing neuroanatomy, biochemistry, and neurophysiology have provided scientists with the biologic means to study complex behavioral patterns.

Cancer

- One of the first studies of chemotherapy and cancer was carried out on dogs and resulted in the first demonstration that some forms of cancer might be caused by an infectious agent.
- Cats have been used to evaluate potential therapeutic techniques in the treatment of lymphosarcoma, adenocarcinoma, malignant lymphoma, multiple myeloma, squamous cell carcinoma, acute lymphoblastic leukemia, aplastic anemia, mammary cancer, and hypercalcemia of malignancy.
- Because of its similarity to human breast cancer, feline mammary carcinoma continues to be an important model for the evaluation of new forms of therapy for breast cancer.
- Rats have served as excellent hosts for the study of transplanted tumors.
- The genetic control of the immune response to cancer has been studied extensively in virally induced cancers and in transplanted tumors in rats.
- The rat has been the major animal used in toxicology screening for carcinogenic compounds.
- Mice have contributed to our knowledge of oncology and the factors that contribute to the initiation, promotion, autonomy, and, sometimes, remission of cancer.
- Early work documented the role of genotype in modulating the frequency and type of neoplasia in the mouse; the H-2 complex, which specifies cell surface antigens and, in turn, histocompatibility, initially was found to affect tumor cell surface antigens in mice.
- The mouse model of human lymphoid cancer holds great promise for future research.
- The retroviruses or lentiviruses that contain RNA-dependent DNA polymerase (reverse transcriptase) were first described in the mouse.

Cardiovascular System

- Much of the information about the microbiology and physiology of bacterial endocarditis has been obtained from experiments in dogs; they are ideal animal models because endocarditis develops naturally in dogs.
- Many inherited cardiovascular defects occur in dogs, including patent ductus arteriosus, pulmonary stenosis, persistent right aortic arch, intraseptal defect, and tricuspid and mitral insufficiencies. All the surgical tech-

niques currently used in humans for treatment of these diseases were tested initially in dogs.

- Surgical techniques for replacement of heart valves and segments of larger arteries using prosthetic devices also were tested initially in dogs.
- Drug therapy to reduce infarct size has been studied using cats and dogs.
- Cardiac pacemaker technology was developed and tested using dogs.
- Many techniques and devices used to assist the failing heart (eg, the left ventricular assist device, the artificial heart, and the intra-aortic balloon pump) were evaluated using dog models.
- The most important model for the study of hypertension in humans has been the rat. Rats develop hypertension spontaneously, and it increases with age; the hypertension is more severe in males and leads to cerebral, myocardial, vascular, and renal lesions similar to those seen in humans. Blood pressure is responsive to control by use of antihypertensive agents in rats in a manner similar to that in humans.
- The rabbit has been used to show the relationship between genetics and blood pressure.
- Since cardiomyopathy in cats closely resembles that in humans, the cat has been used as a model to evaluate new therapeutic approaches.

- Rabbits are an important model for the study of stress-induced cardiomyopathy because there are many similarities between cardiomyopathy caused by stress in rabbits and in humans.
- Because dietary-induced atherosclerosis also occurs in cats, this species has been used as a model of atherosclerosis in humans.
- One of the first links between diet and atherosclerosis were established in studies with rabbits.
- The importance of dietary lipids and lipoproteins as risk factors in the development of atherosclerosis was demonstrated in primates.
- Studies have shown that diets devoid of, or low in, cholesterol can reverse atherosclerosis in monkeys.
- Hypercholesterolemia as a link between coronary heart disease and mortality was first documented in rabbits.
- Research with monkeys exercised on a treadmill indicates that exercise may help reduce cardiovascular disease and slow the accumulation of atherosclerotic plaque even when the diet is high in fat.

- All the techniques used in coronary artery bypass surgery and heart transplantation (including the heart-lung machine) were developed during experiments using dogs.

Childhood Diseases

- Using the monkeys as a test subject in 1953, Jonas Salk developed the killed poliovirus vaccine used in many countries today. In 1959, Albert Sabin developed the live attenuated vaccine currently used in the United

States.

- Therapies for and prevention of beriberi, smallpox, rubella, pertussis, pellagra, measles, mumps, and diphtheria all were pioneered with experiments that used mice, rats, chickens, and dogs.
- A vaccine for chickenpox, developed using animals, currently is undergoing clinical trials in the United States.

Cholera

- The usefulness of drug therapy for the treatment of patients with cholera was determined using dogs.

Convulsive Disorders

- Epilepsy in mice closely resembles that in humans, and biomedical studies in mice have indicated that epileptic brain foci have an increased sensitivity to neurotransmitters.

Diabetes

- Dogs were used in the classic experiments of Sir Frederick Banting and Charles Best that identified insulin as an important hormone in carbohydrate metabolism.
- Canine models of diabetes have led to advances in the treatment of ocular and vascular complications associated with diabetes.
- The technique of pancreatic transplantation was developed in dogs.
- The best model available for the study of spontaneous insulin-dependent (juvenile-onset) diabetes in humans has been the rat.

Gangliosidosis

- Disorders in lipid metabolism are common in cats, which have been used to evaluate therapy for diseases such as Tay-Sachs and Sandhoff in humans.

Gastrointestinal Tract Surgery

- The usefulness of a colostomy for the treatment of gastrointestinal tract cancer was tested in dogs.
- Rapid ambulation after gastrointestinal tract surgery as a means to reduce the formation of adhesions was demonstrated in dogs.
- The control of intestinal motility, the role of the liver and pancreas in digestion, and the production and elimination of gas were delineated in dogs and led to the development of surgical techniques to resect and rejoin the intestinal tract.
- Studies in dogs are under way currently that deal with intestinal immunity, gallstone formation, and improved treatment of fluid imbalance in various disease states.
- Virtually all new suture material currently is tested using dogs.
- Cats were used in the first visualization of the gastrointestinal tract as well as to define the relationship between autonomic neural function and gastrointestinal tract activity.
- The treatment of esophageal achalasia was developed in cats, which have a similar hereditary condition called "mega esophagus."

Hearing

- The pattern of hearing loss associated with age in mice

closely parallels that in humans; therefore, the mouse has been an excellent experimental model for studying age-induced hearing loss in humans.

- The pattern of hearing loss due to noise exposure is parallel in mice and humans, and tests using mice have resulted in the establishment of rules and regulations to limit decibel levels in the environment.

Hemophilia

- Since hemophilia in dogs is nearly identical to that in humans, the dog has been a useful model to study the mechanisms of hemostasis and to determine treatment strategies.
- The first successful cure of a blood disorder by bone marrow transplantation occurred in a mouse; this experiment led to bone marrow transplantation in humans.

Hepatitis

- Because viral hepatitis occurs naturally in dogs, therapy for the disease was assessed in studies in dogs.
- The canine liver is subject to injury by a variety of chemicals, including ethanol; therefore, many comparative studies on cirrhosis in dogs and humans have been performed.
- The world's first hepatitis B vaccine, which was dependent on research with chimpanzees and other primates (since hepatitis B cannot be transmitted to other laboratory animals) became available in 1981.

Infection

- Rats have been used extensively for the study of infectious disease caused by bacteria, fungi, *Mycoplasma*, *Rickettsia*, viruses, and parasites.

Malaria

- Primate studies on the pathogenesis of malaria have shown that all four species of human malaria pathogens have a fourth, or liver, stage that can remain asymptomatic indefinitely until the parasites are released into the bloodstream to produce relapses.
- Potential therapies for malaria, a disease that affects 200 million people worldwide, have been evaluated primarily in primates.

Muscular Dystrophy

- The mouse was the first animal model available to study genetic dystrophies, and early biochemical and physiological studies provide important information on Duchenne type muscular dystrophy.
- A model for muscular dystrophy exists in chickens and has been used for recent studies on therapeutic approaches to the treatment of muscular dystrophy.

Nutrition

- Effective therapy for beriberi resulted from a study of a similar niacin deficiency called "black tongue" that occurs in dogs.
- The dog has been used extensively in the study of rickets and calcium and vitamin D deficiency.
- Treatment of glycogen storage disease with portocaval shunt has been analyzed using dog models.

Ophthalmology

- Many common retinal diseases such as glaucoma,

cataracts, and uveitis occur in dogs. Therefore, dogs have been used as animal models to determine effective therapies for these conditions.

- Studies on the development and function of the visual system in monkeys and cats revealed that these animals, and by implication humans, are not born with a fully developed visual cortex. The maturation of the connections between and within the cells depends on visual stimulation. If deprived of such stimulation, demonstrated when an eyelid is occluded experimentally in a monkey, changes occur in visual neurons in the brain and their connections.
- Research on cats with cataracts has contributed to knowledge about lens structure and function as well as corneal healing after surgery in humans.
- Mechanisms of visual development, plasticity of the visual cortex, and the processes that govern the balance between different visual stimuli that permit the cerebral cortex to integrate information were defined in primates.
- The understanding and treatment of children's visual disorders have been dependent on basic and applied research that uses young primates.

Organ Transplantation

- The dog has been used as the primary model for organ transplantation technology.
- The first successful kidney transplantations were performed in dogs in the late 1950s and have led to transplantation of the liver, heart, lung, and various endocrine organs in humans.
- The immunologic mechanisms involved in tissue rejection were determined in rats and have led to many advances in treatment of rejection.
- Rats have been used to investigate the nature of the immune response in sites such as the anterior chamber of the eye and brain as well as to study the various strategies by which cells, passively administered antibodies, and cyclosporine treatment can enhance graft survival.

Parkinson's Disease

- In 1981, the first animal model for research for Parkinson's disease was developed through the long-term administration of the chemical MPTP (1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine). This compound produces many of the clinical and physiological features of human Parkinson's disease, including the loss of dopamine-producing brain cells.

Pulmonary

- The use of rats has been valuable in determining the effects of air emboli as well as the means to prevent and treat decompression sickness.
- The Blalock-Taussig operation, in which it was shown that the ductus arteriosus could be closed surgically and, thus, cyanosis prevented, was performed initially on dogs.
- The pump oxygenator used during heart and lung operations was developed in dogs.
- Dogs served as models in many of the physiological and biochemical studies necessary to determine the patho-

physiological mechanisms involved in emphysema.

- Pulmonary edema and obstructive lung disease were studied in dogs to develop instruments for clinical measurements to evaluate similar phenomena in humans.
- The treatment of thermal burns of the lung, which often occur in association with chemical ingestion, fires, or automobile or aircraft accidents, was determined using dogs.
- Lung transplantation has been studied in dogs and has resulted in the recent development of surgical techniques for the treatment of end-stage pulmonary disease in man.
- Rabbits were used to prove that tuberculosis is transmissible by both inoculation and ingestion.
- Muroid enteritis in rabbits seems to be an animal model of cystic fibrosis and is being used to develop new and innovative therapeutic regimens.

Rabies

- Louis Pasteur's original work on attenuated vaccines was done through passage in rabbits.

Radiobiology

- The properties of radiation, both as a hazard and as a therapy, have been defined using dogs.
- The earliest experiments on the influences of radiation on physiology were performed in mice.
- Early work using outbred and inbred strains of mice clearly demonstrates (1) that some animals are more radiosensitive than others; (2) that survival of cells in animals is dose dependent, but if the dose is divided over time an increased amount is required to achieve the same effect; and (3) that survival is related to the age at which exposure was first received.
- Experiments in mice have indicated that by reducing the molecular oxygen tension of cells, there is an increase in resistance to radiation, supporting the free-radical hypothesis.

Reproductive Biology

- The rat has been used in studies of reproductive endocrinology and of the morphology and control of the menstrual cycle. The physiological work led to much of our understanding of these processes in mammals.
- Recent studies in mice have documented the fact that there is a link between the pituitary gland and the initiation of menopause.
- Research on primate social behavior has delineated mechanisms responsible for female sexual maturation, reproductive strategies, infant care, and the influence of social, environmental, and biologic factors on reproduction. Results of this research have challenged the assumption that female primates are biologically emancipated from the endocrine influences that govern the reproductive behavior in the majority of mammalian species.
- Primate research also has delineated hormonal and other biologic mechanisms responsible for ovulation, steroid feedback, events governing gonadotropin secretion, adrenarche, puberty and adolescence, sperm maturation and transport, embryonic and fetal development,

fetal exemption from the maternal immune response, and the onset of labor.

- Basic research studies carried out in the primate have led to the development of fertility control methods.
- Alternatives to in vitro fertilization have now been determined in primate research studies. These include low tubal transfer of eggs and surrogate embryo transfer.
- Pregnancy and fetal development have been studied extensively in primates, since they rarely can be investigated directly in humans.
- The identification of Rh (rhesus factor) was an early breakthrough in the area of the immunology of pregnancy and resulted from tests on primates.

Skeletal System, Fracture, and Related Studies

- The intramedullary pin for internal fixation of long bones and skeletal prostheses, including the artificial hip, were developed using dogs.
- The dog also has been used in the study of cartilage and tendon repair and surgical repair in osteoarthritis.
- Fusion of spinal vertebrae in chronic disk disease and surgery to provide relief of pain for herniated disks were procedures tested initially in dogs.
- Development of the skeleton and normal and abnormal growth patterns were first delineated using rabbits.

Spinal Cord Injury

- Long-term paralysis resulting from spinal cord injury has been reversed in cats by administering clonidine; preliminary studies in humans indicate that autonomic dysreflexia can be controlled and spasticity minimized using clonidine.

Toxoplasmosis

- Approximately 4500 infants are born with congenital toxoplasmosis annually in the United States. Virtually all research on this infection has been done using the cat as a research model.

Trauma and Shock

- The dog has been the primary research model used in the study of kidney function and shock as well as of the effects of fluid therapy and resuscitation. Most of the drugs used for cardiogenic shock were produced as a result of studies using dogs.
- Mechanical support measures to increase coronary artery flow in cardiogenic shock and to stimulate the development of intracoronary anastomosis were determined using dogs.
- The treatment of hepatic failure and abnormal metabolism associated with traumatic injury have been studied using dog models. Defense against infection (especially opportunistic infections) and organ failure also have been studied in dogs.

Yellow Fever

- Research with primates has clarified the differences between the urban and jungle types of yellow fever, and studies of yellow fever in monkeys have led to the production of the first yellow fever vaccine, which was devel-

oped specifically from research on the mouse.

Virology

- Understanding of viral diseases, including yellow fever, herpes simplex, rabies, encephalitis, and influenza, was accomplished using mice; sensitive diagnostic procedures to detect infection in humans were developed using mouse models.
- Mice have been used extensively in the study of viral immunity and have played a role in the development of vaccines against influenza, poliomyelitis, encephalomyelitis, eastern equine/western equine/Venezuelan encephalitis, and rabies.
- Chimpanzees were critical in the discovery that a slow virus is the infectious agent of kuru, a fatal brain disorder found in Southeast Asia.
- Primates currently are being used in research on the role of slow viruses in acquired immunodeficiency syndrome, Alzheimer's disease, and other degenerative disorders.

Conclusions

Regardless of the animal model, animals have proved to be invaluable in the pursuit of knowledge in the life sciences, and the knowledge gained often benefits both animals and humans. The director of People for the Ethical Treatment of Animals recently said, "If it were such a valuable way to gain knowledge, we should have eternal life by now." It should be clear, however, that the question should not be "What haven't we learned?" but rather "What have we learned?" Many of today's most vexing health problems will be solved by research on animals. Acquired immunodeficiency syndrome, Alzheimer's disease, coronary heart disease, and cancer represent but a few of this nation's most troubling health problems. In scientific and medical journals, new pieces of information directed toward the conquest of these and other diseases continue to emerge. It is only with continued support for the research process (including funding, animal experimentation, and peer review) that American medicine can continue as a leader into the 21st century.

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Forum: A Response

The following was written in response to an article which appeared in the July 9, 1989, New York Times Forum.

The fact that the health care sector of America's economy is far more successful, faster growing, and competitive in quality worldwide than other sectors such as the automotive industry obviously bothers auto industry spokesmen like Walter Maher ("Forum," July 9, 1989). Highly labor-intensive, health care employs many millions of skilled and unskilled Americans alike, all of whom vote and pay taxes and buy food and clothes and, yes, cars. Abundant health care is something everybody wants and needs; it does them a world of good, particularly if they've been in an accident, or are the victims of life-style abuses such as alcohol, tobacco, or other drugs.

Why does everybody keep dumping on one of the best things America has going for herself? Why should we spend less on health care? So we can spend more on alcohol or cosmetics or car repairs? Which sector is more worthy of support and does more good for the people? The public supports more expenditures for health. It is the bureaucrats and regulators who are constantly devising new ways to deprive people of health care benefits. Perhaps Mr. Maher should tell Arlene Keane (mentioned in the *New York Times'* Good Health Magazine, April 16, 1989) that her seven new joints (two shoulders, two hips, two knees, and one ankle) cost too much, and that this real-life bionic woman shouldn't have danced at her daughter's wedding.

Undoubtedly it is easier for the auto industry to get health care cost concessions out of Congress at the expense of taxpayers, than it is to get them out of the auto unions at the expense of automotive workers. If Canada is such a patient's paradise, why are so many Canadians coming to American medical centers for treatment at their own expense rather than getting on the long waiting lists in their native land? There is no traffic in the other direction. The same goes for England and Sweden and Japan and other "low infant mortality" nations.

The time-worn and patently unfair indictment of America's medical care system because the U.S. "ranks 16th in the world in life expectancy and 17th in infant mortality" is wearing very thin. The tragedy of infant mortality has a lot more to do with the inordinate number of teen pregnancies, poverty, drug and alcohol abuse during pregnancy, and failure to seek (or to accept) even free prenatal care, than it does with the efficacy of our medical care system.

Also, despite the world's best and most accessible

medical technology, U.S. life expectancy is below some other countries, but our lifestyle is the chief culprit. We Americans enjoy the most affluent and most self-abusive life-style in the world, and we have the medical costs to prove it! Perhaps there *is* something to the Japanese proverb that "good medicine always has a bitter taste." Maybe that's why the stoic Japanese lead the world in longevity.

Let me assure Mr. Maher that physicians are cognizant of rising health care costs and concerned about their effect on *everyone*, including American business. But in the name of fairness, still an American virtue, placing responsibility on physicians for the escalating costs of societal ills is akin to blaming the police for more crime. The unfortunate result is the glooming of American medicine, and a conspicuous decline in the morale of those who are giving their patients - us- the best medical care in the world.

Of course American medicine is not perfect, and there are problems to address, but it is the best system in the world, and still getting better. It is funded by a pluralistic system that works very well for most people, but obviously less well for the 35 million who are uninsured. Most of them have no choice, especially the working poor, who are not quite eligible for Medicaid, but unable to afford any private coverage, and their employers provide no benefits. Medicaid, even at its best, has always been woefully inadequate. Fewer than half of this nation's poor qualify for the program mainly because the income limits vary widely among the states. But even the uninsured do not lack medical care when needed; if unpaid for, however, its cost is shifted to those who do pay, in higher fee and higher health insurance premiums. But expanding Medicaid eligibility in all states, and mandating coverage for employees would plug most of the gaps, for starters.

In his capacity as a Chrysler Corporation executive and spokesman, Mr. Maher has merely mouthed the same tired phrases created by bureaucrats to blame others for politicians not keeping their promises. Lest we forget, rich and poor Americans alike demand immediate, quality medical care, with the emphasis on "quality," and their doctors pay the five and six-figure malpractice insurance premiums that prove it. Despite the fact that physicians are more skilled and achieve better results than ever before, malpractice suits still continue to proliferate. Perhaps one of the reasons for this irrational sequence of events is that, as George Bernard Shaw noted: "We have not lost faith but have transferred it from God to the medical profession." As flattering as that may be to physicians, the responsibility is too great; that faith is too short-lived; and unlike God, physicians are not immune to prosecution.

Mr. Maher and like minds in the federal bureaucracy and Congress are proposing that government provide controls over how much health care elderly Americans would be allowed to receive, under the harmless-sounding name of "expenditure targets" (ET's) for Medicare funding. "Expenditure targets" would constitute a radical and deceptive way for government to silently curtail legislated Medicare benefits, a move that must lead to the rationing of health care to those who need it most! This is not a surgically precise cutback; this is throwing the knife blindfolded at a "target" of unknown senior Americans. Health care rationing, long waiting lists, and strict eligibility standards for state-of-the-art procedures would become a reality for senior citizens here, as they long have been in Canada and Britain for everyone. As Dr. Jim Sammons of the AMA said: "If Congress wants to reduce the amount of medical care available to the elderly, they should do it in a straightforward way and then take the heat for it from the voters."

The next step, of course would be to try out "ET"'s in union contracts or health insurance policies or state hospital regulations, as happened with Medicare DRG's, under which physicians are pressured to discharge patients from hospitals "sicker and quicker," while the politician, bureaucrat, or employer responsible for the DRG policy gets to escape blame for its consequences. Of course, the Mr. Mahers of this world will be in a position to escape this rationing imposed on their employees or insureds or constituents, just like their elite counterparts in those "higher longevity" nations. They flock with their loved ones to American medical centers for the best in health care.

Timothy B. Norbeck

Executive Director, Connecticut State Medical Society

BOOK REVIEW

Technology, Bureaucracy, and Healing in America; A Postmodern Paradigm

By Roger J. Bulger, Iowa City, Iowa, University of Iowa Press, 1988. 97 pp.

Roger Bulger has a vision for American physicians and the entire American health care system. That vision is his *Post-Modern Paradigm*, the subtitle of this slender, but significant, volume. The main title, *Technology, Bureaucracy, and Healing in America*, indicates why a new vision may be necessary, for it conveys the inevitable collision among multiple forces that affect health care today. What the title cannot convey, but the text eloquently does, is the tragedy inherent in that collision which is causing society to make agonizing choices about the allocation of increasingly scarce resources.

This lengthy essay will please, but hardly surprise, those who know Roger Bulger. It draws on his long and varied experience in both the healing and the bureaucratic components of American medicine, his insight, his deeply held values and humane instincts, his belief in the

essential goodness of American physicians, and his lucid use of language. Physicians will find familiar much of what he has to say, but his perspective and analysis should bring them new understanding.

At the outset Bulger captures his reader with a lengthy series of juxtapositions of the "just when we thought we had accomplished something great, then look what happened" variety; for instance, just when the conquest of serious infectious disease seemed near, a plague like HIV appeared. The series of paradoxes sets the stage for his description and analysis of the several forces that are creating such turmoil in the health care system.

He analyzes those forces as:

1.) *Technology*, the technologic progress which has vastly increased both capability and cost and has raised the expectations of the public for the cure of any ill. This progress has generated an imperative for the use of technology, often long before its value or cost effectiveness has been proven.

2.) *Healing*, the ancient Hippocratic tradition of medicine on which the concept of service to the patient has developed. It directs the physician to place the interests of the individual patient above all else, even when that interest might run counter to what the physician would consider to be optimal health policy.

3.) *Bureaucracy*, the currently evolving bureaucratic trend in the organization and financing of health care. It is a reflection of the effort to control costs by regulatory, competitive, and corporate strategies. The developments within this "tradition" have placed the contemporary physician in the mainstream of commerce as much as in the traditional role of caring.

Bulger develops all three of these themes as they affect physician behavior, and he frames them on a background of American cultural norms, norms that value individuality and freedom of individual effort, that embody a persistent hope of success (or cure) in spite of prior failure, and that, in their optimism, have created the expectation of universal access to all modalities of care. Our particularly American value system also implies a commitment by the physician to the preservation of basic values and an obligation on the part of the individual to give something back to the larger community. Bulger argues that these characteristics have influenced the way both physicians and consumers have responded to the three forces enumerated above. Since the lectures on which this book was based were given in England, Bulger also makes a number of comparisons between the British and American health care systems which further highlight how different cultural values influence the evolution of professional behavior.

As Bulger analyzes the three forces against this "American" background he concludes that the collision of technology, bureaucracy, and healing has produced conflict and a series of "tragic" choices, ie, decisions about the use of limited goods which sequentially tip toward benefiting one group while denying another, a process that

regularly challenges the precepts of distributive justice. He believes the society has lurched along imperfectly in a series of incremental decisions without a valid larger scheme to guide it. Lucidly and succinctly, he frames the dilemmas in terms of what the health care system can do, what it should do, and what the society wants it to do, and he concludes that by and large we get what we want, whether or not that is best for the society as a whole.

He clearly believes that the present trajectory is destructive, for commerce has come to dominate caring. He holds strongly that there is a great need for physicians to reaffirm the central tenets of the healing tradition while simultaneously recommitting to the needs of the larger society, so that all the people may benefit.

I find Bulger's call to higher values laudable, though his inherent professional idealism may have led him to understate the tendency of physicians and all the current "bureaucratic" players to be subject to the same materialistic motives that drive much of contemporary society. He articulates well the dilemmas and the need for a "postmodern paradigm." But he does not have a very precise prescription to guide society, and medicine within it, to a resolution among the sharply conflicting forces. But, then, no one has formulated a workable, comprehensive solution. Dr. Bulger is also rather forgiving about the flaws in medicine, and he is gentle about the current business orientation of physicians. Yet I admire his belief that they can respond to his call to put the common weal before economic self-interest and to develop again a stronger commitment to the needs of the broader community.

Uwe Reinhardt, the health economist, is not so gentle in his extensive introduction to this book. With his sword-like pen and his legendary wit, he provides a sharp counterpoint to Bulger's commentary, and takes the medical profession seriously to task for putting self-interest ahead of service, especially on economic issues. He sees physicians as having become so immersed in commerce that they will never be able to bridge the gulf between the bureaucratic and Hippocratic imperatives. His comments probably should be read both as introduction and postscript.

Together Bulger and Reinhardt provide significant insight in to the starkness of the dilemmas that our profession and society face in utilizing precious health resources for the greatest common good. If physicians can read both with temper contained, they may gain understanding of the problems as well as appreciation of the views that others hold about physicians.

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Kyle L. Ballou Appointed CSMS Director of Government Relations



Attorney Kyle Lynne Ballou of Hartford has been appointed CSMS Director of Government Relations succeeding Cameron C. Staples who served in that position since 1986. Mr. Staples recently received his law degree and has entered the practice of law.

A native of Rhode Island, Ms. Ballou is a 1981 graduate of Mount Holyoke College and received her Juris Doctor degree from the University of Connecticut Law School in 1985. She served as a law clerk for the Hartford Insurance Group and also in the office of the Connecticut Attorney General.

Since November 1985, Ms. Ballou served as Assistant Counsel for the Connecticut Business and Industry Association (CBIA) and was legislative liaison between the 6,300 member companies and the Connecticut General Assembly. Her various duties included researching, drafting and presenting testimony at public hearings; communicating with members on issues before the Judiciary, Insurance and Real Estate, and the Labor and Public Employees Committees. She also was a contributing editor to the General Assembly Report produced by CBIA.

License Fees Raised "Across the Board"

In the feeding frenzy for new tax revenues, professional license fees did not escape the notice of Connecticut's General Assembly during the waning hours of the recently concluded legislative session.

Following is a listing of the "before and after" fees of various licensed practitioners:

"BEFORE"	GROUP	"AFTER"
\$160	Physicians	\$460
150	Attorneys	450
75	Chiropractors	225
150	Dentists	450
75	Naturopaths	225
100	Optometrists	300
50	Podiatrists	150

Given the chaotic search for additional budget-balancing revenues, there was no way to avoid these increases. CSMS has always maintained that license fees should reflect only the cost of administering each licensing office and not be used for general revenue purposes.



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American Medical Association Annual Meeting 1989



The annual meeting of the AMA was held in Chicago, 18-22 June 1989. Each year the House of Delegates, the policy making body of the AMA, is convened at this meeting. There are 433 elected members in the House, representing state societies and many of the specialty societies. Drs. Stewart J. Petrie, Vincent J. Catrini, Jerome K. Freedman, Edward A. Kamens, and Joseph S. Sadowski are the allotted five delegates from Connecticut. Attending the meeting, in addition, were five alternate delegates, the president, the president-elect, a physician from the Hospital Medical Staff Section, and Resident and Student Section Members.

The House of Delegates functions in a very democratic fashion. A speaker, vice-speaker, trustees, council members, and a president are elected to terms of varying lengths. The business of the House, discussion and debate on matters of policy, is conducted upon receipt of recommendations from its Reference Committees. Any

AMA member, county or state society, or specialty organization may submit resolutions to the House of Delegates. These resolutions are assigned to one of several five member Reference Committees for consideration. An entire day is committed to the Reference Committees which meet concurrently to hear testimony on these resolutions. At this meeting 273 resolutions were considered. Our representatives testified at several of these hearings. The committees' recommendations, arrived at in executive session later that evening, were printed and available for the House of Delegates during the remaining two and one-half days.

A brief statement about some of the issues is in order. After prolonged discussion about financing health care for the indigent and uninsured, including consideration of the problems with a national health system, on the one hand, and possible hardships to small employers, on the other, the House voted "that the AMA endorse the concept of a phased-in requirement that employers (limited initially to larger employers) provide health insurance coverage *within the private sector* for all full-time employees, with coverage expanding over several years and with a program of diminishing tax credits or other incentives to avoid adverse effects on employees," and that there be a further study of this. This was noted in the press as a significant new direction for the AMA, as indeed it is.

Medicare reform was another intensely discussed subject. Strong opposition was voiced to mandatory assignment and to mandatory assignment as a condition of licensure, to discrimination against Medicare nonparticipating physicians, to the use of referring physicians identification numbers on claim forms, and to DRG payment differentials between rural and urban care. The most vigorously opposed concept of all was that of expenditure targets which most certainly would become expenditure caps and inevitably lead to the rationing of medical care. On the more positive side a major effort will be made with HCFA through the Board of Trustees to define the term *medical necessity*, refine and clarify CPT-4 codes, make Medicare language simpler and more easily understood, and establish parameters of practice in place of expenditure targets.

The medical care of our patients was discussed in a more informed, more reasoned manner as befits physicians' greater knowledge in this area. There was a valuable exchange of information and ideas. Environmental pollution, including air and water pollution, toxic substances, the "Greenhouse effect," and stratospheric ozone depletion was addressed in a series of actions. HIV disease was recognized as an epidemic requiring more aggressive Public Health Department measures in testing and counseling. A 1987 landmark AMA report on AIDS will be updated. The delegates voted to urge restrictions on alcohol advertising and its availability to minors, further limits on the use of tobacco products, and controls on the sale of "assault weapons."

Perhaps this brief report touching some of the highlights will give you a "feel" for the variety and complexity of the issues considered and the reasonableness of the delegates decisions. It was an exciting meeting.

Roger S. Beck, M.D.
President

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Harper's Fifth Reader: Common Ground

ROBERT U. MASSEY, M.D.

In his notorious farewell address at Johns Hopkins University in 1904, Sir William Osler, observed that "...the history of the world shows that a very large proportion of the evils may be traced to the sexagenarians—nearly all the great mistakes politically and socially, all the worst poems, most of the bad pictures, a majority of the bad novels, not a few of the bad sermons and speeches." Recent political events here and abroad have left little doubt that Osler was right, at least about politics.

For most of us sometime after our middle years the times seem to slip out of joint, and the remembered past takes on a roseate glow. If we forget that this has been so for every generation, we may fall into the role of a common scold, boring young people with tales of how splendid the world used to be, and imputing responsibility to them for its current wretched state.

When I find myself complaining that college students, as well as medical and high school students, seem ignorant of history, literature, art, and science, although they know all about computers and AIDS, I sometimes recollect how tiresome a scold can be, even to himself. But then, when I read how our students compare with those from other countries and find them at the bottom of the heap on standardized tests, I wonder whether I may not be right.

Several days ago I came upon a copy of *Harper's Fifth Reader* that had been my uncle's in 1899 when he was in fifth grade. It was a thoroughly beat up book, probably from being carried the several miles back and forth between farm and village, but underlined words and notes in the margins bore witness to heavy use as well. The only language in his Mennonite home was German, sometimes Dutch for parental secrets: most of the neighboring farm families were also German. The school, of course, was not bilingual, nor would the community have wanted that.

The Publisher's Note declared that the *Reader* was "...distinctively an American book,...by leading American authors,...and of living interest to American read-

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ers." There follows an unembarrassed statement of the purpose of public schooling: "To cultivate a spirit of patriotism and to inculcate a commendable pride in the achievements of our countrymen is one of the first duties of schools." They might have added, "to teach young Americans from immigrant families to read and to be familiar with a common cultural heritage," but that would have been to assert the obvious.

The fame of some of the authors has faded after a hundred years (publication date: 1889); others are well known to me but to few high school students I have asked: Hawthorne, Melville, Whittier, Cooper, Greeley, Channing, Holmes, Lanier, Cable, Webster, Longfellow, Wallace, Bryant, Hale, Hearn, Howe, Whitman, Emerson. The selections are not abridged; in a few instances difficult words are defined: rubicund, termagant, remonstrate, gangrene, vehement; there are biographical notes and references to classical sources. The students are expected to know how to look up Biblical quotations and names. I read many of these same selections 40 years later, but in the 10th grade, not in the fifth. The decline of learning appears to have been gradual until recently.

These essays, stories, and poems are by no means "value neutral"; they all are rooted in European and American traditions that have their ancient origins in the lands around the eastern Mediterranean, and to that extent their world view may seem narrow to us today. The intention was not only to produce good readers—the pupil was encouraged to read aloud—but to introduce fifth graders to a small part of the vast treasure-house of Western cultural lore, and, without apology, to hold up in these stories examples of virtue as guides to living a life. This kind of education was closer in purpose to that of fifth-century Athens than late twentieth-century America.

There comes a time in later life when the future appears to take on unrecognizable and threatening shapes, when it seems too late in the day even to scold; we remind ourselves that this is characteristic for sexagenarians. And still there lingers the nagging hunch that this time may be different, that more than the millennium may be ending.

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After *McConnell*: The Process Continues

JOSEPH M. HEALEY

THOUGH the Connecticut Supreme Court's decision in the *McConnell* case failed to satisfy many advocates on either side of the issue, it nonetheless has had several beneficial effects. First, it allowed the wishes of the patient to be carried out by her family. Though some sought to raise doubts about the precise nature of the patient's wishes, the lead opinion of Chief Justice Peters concluded that it could not have been clearer that Mrs. McConnell desired that her family not prolong her life, should she ever suffer an injury leaving her in a vegetative state. Furthermore, each member of her family testified "absolutely, without hesitation" that Mrs. McConnell did not believe in life support systems, including gastrostomy tubes for herself, and that the family was seeking to carry out her wishes. The decision of the Connecticut Supreme Court permitted this to be done.

Second, it represents the unanimous decision of a state supreme court, with the lead opinion authored by its Chief Justice, dealing with an issue which has divided the court of highest jurisdiction in at least two other states. This may well have been the greatest achievement of Chief Justice Peters: to author an opinion which united, rather than divided, the sitting justices in support of the patient's right of self-determination.

Finally, the opinion provides a useful foundation for the continuing discussion and evolution of Connecticut's public policy in this area. It should be quite clear that this will not be the last word on this subject. Within the lead opinion of Chief Justice Peters and the concurring opin-

ion of Justice Healy, there is much fruit for further discussion and for development of the patient's right to refuse treatment.

Complicating Connecticut's attempts to deal with these issues is the fact that the United States Supreme Court will review a case in its next term which raises similar issues to those raised by *McConnell*. While national attention during the closing days of the United States Supreme Court term was focussed primarily on abortion, the Supreme Court unexpectedly granted review to a Missouri case dealing with withdrawing artificial nutrition from an incompetent patient. The case, *Cruzan v. Harmon*¹ involves two major questions: (1) whether a surrogate may order that nutrition and hydration be withdrawn from an incompetent patient who is in a persistent vegetative state; (2) the extent to which a state's interest in life, expressed in that state's living will statute, can override the constitutional right of an incompetent patient to refuse treatment. The manner in which the United States Supreme Court handles this case may well lead to a reexamination of the federal constitutional rights of patients, their families, and their caregivers, and may even lead to further reexamination of the common law and state constitutional rights to refuse treatment. In any event, it is likely that there will be a good deal more discussion about artificial nutrition and hydration during the coming year, and it is certain that this issue has joined the abortion issue as part of the unfinished agenda in health policy.

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

REFERENCE

1. *Cruzan v. Harmon*, 760 SW 2d 408 (1988).

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From the Executive Director's Office

COUNCIL MEETING

Wednesday, July 26, 1989

Attendance

Present in addition to the Chairman, Dr. Joseph C. Czarsty were Drs. Beck, Blum, Bobruff, Catrini, Eslami, Fox, Hollister, Jr., Kamens, Kaufmann, Keating, McDonnell, Meridy, Orphanos, Petrie, Reyelt, Jr., Robbins, Rose, Schwartz, Sosa, Wetstone, Zanker, Zeppieri and Zlotsky.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Sullivan, Ms. Ballou, Ms. Connelly, Mr. Tomat (FCMA), Ms. DeLauro (HCMA) and Mr. Freberg (NHCMA).

Absent were: Drs. Ahamed, Bonner, Chmieski, Dardick, Freedman, Lesnik, Parikh, Petro, Redmond, Sadowski, Welch and Mrs. David Reed.

Reports on Related Organizations

CPRO: Dr. Kamens reported on CPRO activities and on national legislation recently reported out of the House Energy and Commerce Committee which is responsible for PRO legislation. It was reported that some of the issues to become familiar with over the next few months are the following changes that will be handed down by Congressional legislation:

- (1) Provision for reconsideration process for physicians in denials for quality of care and changes in the wording of the quality of care denial letters to beneficiaries.
- (2) Limitations on civil fines associated with sanction activities.
- (3) Development of an agency for health care research and policy which would focus on research on outcomes of care and practice guidelines.

Data being compiled would suggest that Connecticut has been an outstanding state in terms of appropriate utilization of application of services and length of stay.

Report of the President

Dr. Beck reported on the President's dinner held on June 27 which was attended by county presidents and leaders of the specialty sections. The subjects discussed at the meeting were CPRO, CMIC, MDHP, legislative issues, and the actions taken at the recent AMA meeting. This meeting was a follow-up of the meeting initiated last year by Dr. Zlotsky, which was an effort to urge the county associations and specialty groups to work together so that presentations to any external force, specifically the Connecticut legislature, will represent a common front so that when there is need to testify on any bill, it can be done with one voice.

Dr. Beck requested Dr. Wetstone, Chairman of the

Committee on Legislation, to report on a meeting that he, Dr. Wetstone and the CSMS lobbyist held the previous evening with a group of neurologists. He reported that Connecticut is one of the few states in the nation that requires physicians to report the name of any patient who suffers with epilepsy when he sees him for the first time, whether or not he had been in therapy for many years previously. This action many times affects doctor-patient relationship and has also resulted in some law suits. This issue will be discussed by the Legislative Committee and its decision as what action should be taken will be brought back to the Council for their consideration. He further reported that it was his intent to meet with as many special interest groups as possible well in advance of the legislative session so that any issues arising may be resolved prior to the beginning of the session.

Report of the Executive Director

Tim Norbeck introduced Attorney Kyle L. Ballou of Hartford who has been appointed CSMS Director of Government Relations succeeding Cameron C. Staples, who recently received his law degree and has entered the practice of law.

Mr. Norbeck also reported on the following items:

- (1) He discussed AMA strategy against the "expenditure targets" (ETs) advanced by the House Ways and Means Committee as a way of controlling Medicare costs. The AMA ran an article and ad in the Washington Post pointing out the rationing implication of ETs. In addition, the AMA also directed mailers to 185,000 members and 105,000 nonmembers. Mr. Norbeck also pointed out that the House Energy and Commerce Committee approved its own Medicare budget package without the inclusion of "expenditure targets". In the next few weeks the Senate Finance Committee will come out with its own version and then a conference committee will work out the difference. A copy of Mr. Norbeck's response to an article appearing in the New York Times on Medicare reform and ET's was distributed to members of the Council.
- (2) Mr. Norbeck mentioned that the Bush Administration was having difficulty replacing William Roper, M.D., as head of HCFA. A second candidate, Drew Altman of New Jersey withdrew and accepted a job with a foundation after the first candidate was forced to withdraw, due to a conflict of interest charges.
- (3) CSMS staff asked the Society's legal counsel, Wigin and Dana, to prepare updates on the Kadish peer review matter, AIDS, and abortion issues, and these reports were distributed to the Council and will be included in a forthcoming newsletter.

Report on the AMA Meeting

A summary of the 1989 Annual Meeting of the AMA House of Delegates was distributed to all members of the Council and Dr. Stewart Petrie highlighted some of the issues presented at the meeting which were:

- (1) The address of Louis W. Sullivan, M.D., Secretary, Department of Health and Human Services, who called for "nothing less than a reformation of the American health care system as we know it today." Dr. Sullivan stated that the Administration's views on physician payment reform under Medicare included support for a three part framework: (a) a resource-based fee schedule; (b) an expenditure target for Medicare physician services; and (c) beneficiary protections. Dr. Sullivan called on physicians to become involved in seeking solutions to America's health care problems.
- (2) The address of James H. Sammons, M.D., AMA Executive Vice President who reported on the growing challenge to the American Health Care System. He said, "If there is anyone who believe that rationing of health care cannot happen in this country, he would tell them to pay attention to what is already happening in Washington. It appears that all proposals from Washington are recommending expenditure targets. The experience of Canadians with expenditure targets have led to long waits for necessary surgery, degrading conditions for elderly hospital patients, and in some cases even premature deaths while waiting for operations. Dr. Sammons urged physicians to call their elected representatives and inform them how ETs will affect their constituents.
- (3) Expenditure Targets (ETS): This issue dominated the delegate's attention through out the meeting. ETs are government set expenditure goals for total physician services under Medicare Part B and the purpose of the targets is to reduce the amount of physician services the government pays for. They are designed and justified by the Physician Payment Review Commission (PPRC) and others, based on the need to reduce the Federal deficit. Following lengthy discussion, the AMA House of Delegates adopted a resolution urging Congress to incorporate the following considerations when applying budgetary controls to medicare in place of ETs.
 - (a) Assure a high priority to health care for Medicare patients in relation to other programs when allocating federal funds.
 - (b) Given Medicare's finite resources, develop a mechanism to channel those resources to those patients with greater financial need and to require a proportionately larger financial contribution by the more affluent towards their own health care.
 - (c) Reduce the cost of defensive medicine (approximately \$20 billion a year) caused by the present tort system.

- (4) Resource-Based Relative Value Scale for Physician Services (RBRVS): The House adopted a resolution that called on the AMA to develop and aggressively seek Congressional sponsorship and support for federal legislation that would allow AMA and the state medical associations, on behalf of physicians, to negotiate payment schedules on federal and state policies respectively, impacting on physician reimbursement. The Federal Trade Commission has prevented physicians from negotiating any payment schedules.
- (5) Strengthening the U.S. Health Care System: The AMA Board of Trustees announced a major initiative involving the commitment of substantial resources to ensure that the superiority of the U.S. health care system is maintained. The initiative will also include significant resources to see that the public and others are fully aware of the advantage of American medicine. Key programs include Medicaid expansion, coverage for the uninsured, and Medicare reform.

Dr. Petrie thanked the delegation and staff for all their efforts at the meeting in carrying out the various responsibilities assigned to them.

Claims Made "Tail" Coverage

Dr. Eslami submitted a copy of a report on the meeting of the Physicians Insurance Association of America (PIAA) outlining the problem for young mobile physicians, residents and interns, "moonlighters" and locum tenens regarding purchase of "tail" coverage under claims made policy. Dr. Eslami reported that this issue was raised at the CSMS House of Delegates meeting and the PIAA and AMA is currently investigating the scope of the problem and exploring potential remedies. Currently, the only financially sound option available to some physicians crossing state lines or making career changes is the purchase of "tail" coverage and the purchase of a claims made policy at a claims made, year 1 premium from another source. CMIC has been assured by the AMA leadership that they will be kept apprised of any AMA recommendations or programs that follow from the investigative process now underway. Dr. Eslami reported that there was no real solution to the problem which is immense, and if it is going to be solved it will have to be by the PIAA which incorporates 41 insurance companies that cover 180,000 physicians. CMIC has initiated a program to go to all of the hospitals to address residents and house staffs in regarding claims made insurance and all of the other ramifications entailed in this type of insurance. It was VOTED to accept the report as information. It was also VOTED that Dr. Eslami prepare an article on this subject for distribution to the general membership through *Connecticut Medicine*.

Task Force on Health Insurance for Uninsured

According to the state statute, one physician is to be appointed to serve on this task force, and although CSMS had been requested to suggest a nominee, it later

came to light that the physician had already been nominated by a legislator and appointed. Following discussion, it was VOTED that CSMS write the appropriate authority regarding this task force and recommending the appointment of a physician, on our recommendation, with the explanation that this would more accurately provide for the input of organized medicine. It was further VOTED to submit the names of Steven Wolfson, M.D., New Haven and Paul Dolinsky, M.D., of West Hartford, as nominees for this post.

Report on AMA Hospital Medical Staff Assembly

It was VOTED to receive as information with commendation, a report submitted by Howard W. Meridy, M.D. on the subject meeting held in Chicago on June 15-19, 1989. Dr. Meridy reported that a CSMS/HMSS resolution, concerning membership on the Residency Review Committee, had been approved by the AMA/HMSS and was forwarded to the AMA House of Delegates.

Mandated Health Coverage

Dr. Orphanos reported that the *New York Times* published an article that state legislatures had passed 600 laws aimed at expanding the health benefits offered by many employers. The Health Insurance Association, a trade group in Washington, has stated that are already 314 bills this year to expand public and private health insurance. The National Federation of Independent Businesses reported, that for the smallest firm which typically employs three workers or less, there is no insurance product that is financially viable. He further reported that at the federal level, there are proposals that would require employer health insurance but would eliminate state mandate.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on July 26, 1989. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for purusal by any interested member of the Society.*

Sterilization of the Mentally Incompetent

The Connecticut Medical Examining Board is concerned that some obstetrician/gynecologists are unaware of the laws governing sterilization of the mentally incompetent.

Section 45-78q of the Connecticut General Statutes prohibits the sterilization of *any* person under the age of eighteen. The statute further provides that sterilization of the mentally incompetent can be performed only after a determination of a *probate court* that the person is able to give informed consent to the procedure or, if the court determines that the person is unable to give informed consent, only after the *court's* determination that sterilization is in the best interests of the incompetent person.

Sterilization of the mentally incompetent without authorization by the probate court can result in serious civil and professional liability for physicians who knowingly or unknowingly violate the statute.

If there are any questions about this statute, or any other, please contact Kyle L. Ballou, Esq. at CSMS, 865-0587.

NEW MEMBERS

Members of the Connecticut State Medical Society join in welcoming these new members into a progressive state medical organization. CSMS is dedicated to promoting the science and art of medicine, the protection of the public health, and the betterment of the medical profession. Each new member is encouraged to join with other CSMS members at both the county and state levels in achieving these goals.

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Kenneth J. Egan, M.D., Ridgefield
Alan T. Falkoff, M.D., Stamford
Steven A. Fisher, M.D., Stamford
Joan T. Gewirtz, M.D., Greenwich
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Efrain Gomez-Zapata, M.D., Stamford
Stanley P. Gulin, M.D., Norwalk
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CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

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Full or part time position available in established south end (of Hartford) Walk-In Medical Care Center. Competitive salary; excellent hours (no weekends); incentive bonuses and buy-in options. Please send CV to David R. Howlett, M.D., Two Plymouth St., Hartford, CT 06114 or phone (203) 247-9454.

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FOR SALE: Well established Family Practice. Excellent location and opportunity in central Connecticut. Write, CSMS, c/o FP/JL.

Connecticut—Fairfield County—Family practitioner to join two physician's practice. Located in Danbury area (last year *Money Magazine's* best city in U.S.A. for quality of life). Enjoy the countryside and be within reach of New York and Boston. Excellent salary and fringe benefits; potential long-term association. Teaching hospital with 540 beds. Easy on call schedule. Immediate opening. Call (203) 426-1818 or send C.V. to: Family Health Care Center, 19 Church Hill Rd., Newton, CT 06470.

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Family/General Practice in Ambulatory Care Centers providing acute and continuing care at two locations in Connecticut. Well-rounded medical background and excellent patient relation skills required. Full time position currently available. Competitive compensation, enjoyable work settings, and pleasant ancillary staff. Send CV to David E. Wilcox, M.D., FACEP, Medical Director at PhysicianCare, 28 Main St., East Hartford, CT 06118 (203) 569-8644 or PhysicianCare, 60 Church St., Yalesville, CT 06492 (203) 284-9099 or call for further information.

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Retiring doctors office, live-in or rental apartment above. Established practice of 40 years. Well-equipped office; including records. Water-view. Three blocks from Yale-affiliated hospital. Several financial benefits. Excellent for all solo practitioners. Area needs surgeons. Center of cultural and recreational facilities. R.C. Olsen, M.D., New London, CT (203) 443-0933.

INTERNAL MEDICINE

Established, profitable, part time internal medicine practice available for sale. Downtown New Haven area. Patient parking, medical/office equipment and supplies optional. Interested parties send inquiry to CSMS, IM/QB.

Internist needed to join busy young internist in private practice in a charming community in western Connecticut. Salary guarantees leading to partnership. Send resume to: Dr. Stephen Spear, 30 Quaker Farms Rd., Southbury, CT 06488.

Internist to join two young BC internists in Stamford, CT group practice. Immediate opening to replace retiring physician and assume established practice. Competitive salary w/incentive; retirement plan. Early partnership possible. Please respond to CSMS, c/o IM/PP.

BC/BE internist wanted to join well-established three BC internal medicine group, including broad-based office and hospital practice, and substantial geriatric commitment with SNF based physician's assistant. Liberal salary and benefits. Salary initially leading to partnership. Located in New Haven suburb. Send CV and salary requirements to CSMS, c/o IM/NO.

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Aug. '89. Age 34. Nat'l bds. AB elig. MD, College of Physicians & Surgeons, Columbia University, New York, NY; Int. and Res., The Mount Sinai Medical Center, New York, NY. Prefers group or associate type practice in a medium to large-sized community. Write CSMS, c/o RA/SUR.

INTERNAL MEDICINE

July '89. Age 28. Licensed in Connecticut. Nat'l bds. AB elig. MD, Brown Medical College, Providence, RI; Int. and Res., St. Francis Hospital, Hartford, CT. Prefers southwestern Connecticut. Write, Emilio Melchionna, M.D., Apt. C-1, 20 Gillett St., Hartford, CT 06105.

Oct. '89. Age 30. FLEX. AB elig. MD, University of Iowa, Iowa City, IA; Int., St. Joseph's Hospital, Phoenix, AZ and Children's Hospital, San Francisco, CA; Res., Children's Hospital. Prefers group or associate type practice within commuting distance of the New London/Groton area. Write, Josie Tebben, M.D., 3266 California St., #102, San Francisco, CA 94118.

Feb. '90. Age 36. Licensed in Connecticut. MD, The Hebrew University—Hadassah, Jerusalem; Int., Sackler School of Medicine, Telhashomer, Israel; Res., Kaplan Hospital, Hadassah Medical School, Israel (IM); Fellowship, Bellinson Medical Center, Sackler School, Israel and Albert Einstein College of Medicine, NY (CARD). Open to any type practice and location. Write, SA/IM.

PATHOLOGY

July '89. Age 40. Licensed in Connecticut. Presently in practice. Nat'l bds. AB elig. MD and Res., Cebu Institute of Medicine, Philippines; Res. (PED), Youngstown Hospital, Ohio; Fellowship, Roswell Park Memorial Institute, Buffalo, NY. No preference to type or size of practice. Write, Virgil T. Rona, M.D., Apt. 3D, 19 Linwood Ave., Buffalo, NY 14209.

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INFORMATION FOR AUTHORS

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Titles and Author's Names

The first page of the manuscript should include (A) title of paper; (titles should be short, specific, clear, and amenable to indexing); (B) name of author(s), including first name(s) and with academic degree(s); (C) List hospital positions for each author and any institutional or other credits. If an author's present affiliation is different from the affiliation under which the work was done, both should be given. Include academic appointments when applicable.

Authors should express all measurements in *Système International (SI)* units, but they may include older conventional units in parentheses if they desire.

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The second page should contain an abstract of not more than 150 words. This abstract should be factual, not descriptive, and should present the reason for the study, the main findings (give specific data if possible), and the principal conclusion. Do not include a summary.

References

The following minimum data should be typed double-spaced: names of all authors, complete title of the article cited, name of journal abbreviated according to *Index Medicus*, year of publication, volume number, and first and last page numbers. All

references must be cited in the text. They should be arranged according to the order of citation, and not alphabetically. All references must be numbered consecutively. Numbered references to personal communications, unpublished data and "in preparation" are unacceptable. If absolutely essential, such material may be incorporated in the appropriate place in the text or as a footnote. Sample references are as follows:

1. Jones J: Necrotizing *Candida* esophagitis. *JAMA* 1980;244:2190-2191.
2. Kremer H, Kellner E, Schierl W, et al: Ultrasonic diagnosis in infiltrative gastrointestinal diseases. *Dtsch Med Wochenschr* 1978;103 (June 9): 965-966. Abstracted, *JAMA* 1978;240:2784.
3. Influenza vaccine—recommendations of the Public Health Service Advisory Committee on Immunization Practices. *MMWR* 1979;28:231-238.
4. Fischer DH: *Growing Old in America*. New York, Oxford University Press, 1977, pp 210-216.

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Data presented in tables should be self-explanatory and should supplement, not duplicate, the text or figures. Excessive tabular data are discouraged. Each table should be typed double spaced, including all headings, on separate sheets of 8½ x 11-inch paper. Oversize papers should not be used. Instead, repeat heads and stubs on a second sheet for tables requiring extra width. Number tables consecutively with respect to citation in the text. Each table must have a title.

Illustrations

Figures should be professionally drawn and photographed, if possible. Glossy, clear black and white photographs should be submitted.

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Review and Action

All manuscripts are subject to review by referees in appropriate fields of medicine. Authors are usually notified within three to six weeks as to the acceptability of a manuscript, but sometimes longer delays are unavoidable.

AROUND THE STATE

Award

On 10 June 1989, Morton F. Reiser, M.D., of the Department of Psychiatry at Yale University School of Medicine received the Daniel Drake Medal from the University of Cincinnati. The Daniel Drake Medal is awarded for "outstanding or unique contributions to medical education, scholarship or research. Those chosen to receive the Medal have achieved the standards of excellence all of us strive for in our lives."

Conference

A full day conference entitled "Rationing Health Care: Will It Happen in the 1990s And How Will It Alter Medical Practice?" will be held at the Farmington Marriott Hotel on Monday, 13 November 1989. This program is sponsored by the University of Connecticut School of Medicine, Department of Surgery in collaboration with the Departments of Medicine and Community Medicine and will include presentations by national authorities on health care management and utilization control. For information call Diane O'Reilly at the University of Connecticut, (203) 679-2292.

Roy V. Erickson, M.D., has been named the first full-time medical director of McLean Home in Simsbury.

Esmail K. Faiaz, M.D., of Avon, was recently elected president of the Greater Hartford Obstetrical and Gynecological Society, Inc.

Malcolm A. Galen, M.D., of Simsbury, Coordinator of Nephrology at St. Francis Hospital & Medical Center, has been elected to a two-year term as Chairman of the End Stage Renal Disease Network of New England, Inc.

Lenworth M. Jacobs, M.B.B.S., director of EMS/Trauma at Hartford Hospital, was named Connecticut State Police Surgeon by State Police Commissioner Lester J. Forst.

Melville P. Roberts, M.D., was elected President of the New England Neurosurgical Society at its annual meeting in Boston on May 26.

Daniel Scoppetta, M.D., received a letter of commendation and appreciation from the Connecticut Association of Secondary Schools for volunteer help as the on-site medical official for state-sanctioned athletic events in the Bristol community.

Michael Whaley, M.D., was recently elected Chairman of the Department of Cardiology at Bristol Hospital.



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3. The use of potassium salts in patients receiving diuretics for uncomplicated essential hypertension is often unnecessary when such patients have a normal dietary pattern. Serum potassium should be checked periodically, however, and if hypokalemia occurs, dietary supplementation with potassium-containing foods may be adequate to control milder cases. In more severe cases supplementation with potassium salts may be indicated.

CONTRAINDICATIONS: Potassium supplements are contraindicated in patients with hyperkalemia since a further increase in serum potassium concentration in such patients can produce cardiac arrest. Hyperkalemia may complicate any of the following conditions: Chronic renal failure, systemic acidosis such as diabetic acidosis, acute dehydration, extensive tissue breakdown as in severe burns, adrenal insufficiency, or the administration of a potassium-sparing diuretic (e.g., spironolactone, triamterene).

Wax-matrix potassium chloride preparations have produced esophageal ulceration in certain cardiac patients with esophageal compression due to enlarged left atrium.

All solid dosage forms of potassium chloride supplements are contraindicated in any patient in whom there is cause for arrest or delay in tablet passage through the gastrointestinal tract. In these instances, potassium supplementation should be with a liquid preparation.

WARNINGS: Hyperkalemia—In patients with impaired mechanisms for excreting potassium, the administration of potassium salts can produce hyperkalemia and cardiac arrest. This occurs most commonly in patients given potassium by the intravenous route but may also occur in patients given potassium orally. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic. The use of potassium salts in patients with chronic renal disease, or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustment.

Interaction with Potassium-Sparing Diuretics—Hypokalemia should not be treated by the concomitant administration of potassium salts and a potassium-sparing diuretic (e.g., spironolactone or triamterene) since the simultaneous administration of these agents can produce severe hyperkalemia.

Gastrointestinal Lesions—Potassium chloride tablets have produced stenotic and/or ulcerative lesions of the small bowel and deaths. These lesions are caused by a high localized concentration of potassium ion in the region of a rapidly dissolving tablet, which injures the bowel wall and thereby produces obstruction, hemorrhage or perforation.

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Metabolic Acidosis—Hypokalemia in patients with metabolic acidosis should be treated with an alkalinizing potassium salt such as potassium bicarbonate, potassium citrate, potassium acetate, or potassium gluconate.

PRECAUTIONS: The diagnosis of potassium depletion is ordinarily made by demonstrating hypokalemia in a patient with a clinical history suggesting some cause for potassium depletion. In interpreting the serum potassium level, the physician should bear in mind that acute alkalosis per se can produce hypokalemia in the absence of a deficit in total body potassium while acute acidosis per se can increase the serum potassium concentration into the normal range even in the presence of a reduced total body potassium. The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease, or acidosis requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the electrocardiogram, and the clinical status of the patient.

Laboratory Tests: Regular serum potassium determinations are recommended. In addition, during the treatment of potassium depletion, careful attention should be paid to acid-base balance, other serum electrolyte levels, the electrocardiogram, and the clinical status of the patient, particularly in the presence of cardiac disease, renal disease, or acidosis.

Drug Interactions: Potassium-sparing diuretics; see **WARNINGS**.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term carcinogenicity studies in animals have not been performed.

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Nursing Mothers: The normal potassium ion content of human milk is about 13 mEq per liter. Since oral potassium becomes part of the body potassium pool, so long as body potassium is not excessive, the contribution of potassium chloride supplementation should have little or no effect on the level in human milk.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: One of the most severe adverse effects is hyperkalemia (see **CONTRAINDICATIONS**, **WARNINGS**, and **OVERDOSAGE**). There have also been reports of upper and lower gastrointestinal conditions including obstruction, bleeding, ulceration, and perforation (see **CONTRAINDICATIONS** and **WARNINGS**); other factors known to be associated with such conditions were present in many of these patients.

The most common adverse reactions to oral potassium salts are nausea, vomiting, abdominal discomfort, and diarrhea. These symptoms are due to irritation of the gastrointestinal tract and are best managed by taking the dose with meals or reducing the dose.

Skin rash has been reported rarely.

OVERDOSAGE: The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired or if potassium is administered too rapidly intravenously, potentially fatal hyperkalemia can result (see **CONTRAINDICATIONS** and **WARNINGS**). It is important to recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration and characteristic electrocardiographic changes (peaking of T-waves, loss of P-waves, depression of S-T segment, and prolongation of the QT-interval). Late manifestations include muscle-paralysis and cardiovascular collapse from cardiac arrest.

Treatment measures for hyperkalemia include the following:

1. Elimination of foods and medications containing potassium and of potassium-sparing diuretics.
2. Intravenous administration of 300 to 500 ml/hr of 10% dextrose solution containing 10–20 units of insulin per 1,000 ml.

3. Correction of acidosis, if present, with intravenous sodium bicarbonate.

4. Use of exchange resins, hemodialysis, or peritoneal dialysis.

In treating hyperkalemia, it should be recalled that in patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity.

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Surgery by Non-Surgeons: Podiatric Surgery in Connecticut

JOHN C. RUSSELL, M.D.

ABSTRACT—In order to determine the standards for credentialing, privilege delineation, and quality assurance of podiatric surgery in Connecticut, a questionnaire was mailed to all acute care hospitals, with a 100% institutional response. Of 38 hospitals, 25 currently have granted clinical privileges to podiatrists. Full podiatric surgical programs exist in 12 hospitals; multitiered privileges in seven hospitals differentiate podiatrists with and without postgraduate surgical residency training. Credentialing, privilege delineation, and quality assurance generally is conducted through the chief of surgery or chief of orthopedics, with participation of staff podiatrists. Based on the Connecticut experience, recommendations are made regarding establishment of new podiatric surgical programs.

THE scope of podiatric practice, including surgical procedures appropriate for podiatrists with postgraduate residency training, is defined by statute in each state. The Joint Commission for Accreditation of Healthcare Organizations (JCAHO), in its *Accreditation Manual for Hospitals*, broadly outlines the mechanisms by which podiatrists, as well as physicians, osteopaths, dentists, and other health professionals, are to be credentialed, their clinical privileges delineated, and their clinical behaviors and outcomes monitored through a hospital-based quality assurance program.¹ Yet within any single state, a podiatrist will encounter significant local variation in his access to acute care hospitals, especially if he wishes to perform surgical procedures that are consistent with his training and that require postoperative hospitalization. Reasons for this variability include the different perceptions by hospital medical staffs of the need for podiatric surgical services within their community and concerns regarding the malpractice exposure of physicians participating in the credentialing, delineation of privileges, or quality assurance activities of nonphysicians. Where podiatric surgical practice impinges upon traditional medical disciplines (general surgery and or-

thopedic surgery), quality of care issues are also usually articulated. Because practitioners in traditional surgical disciplines have a broader medical background by virtue of their training (four years of medical school and a minimum of five years of postgraduate residency training) it is felt that these surgeons must, by definition, deliver a better standard of care than a podiatric surgeon when they perform the same surgical procedure as a podiatric surgeon.

In the process of establishing a podiatric surgical activity in our hospital, where podiatrists already had been eligible for full medical staff privileges but had not been engaged in surgical practice, a questionnaire was mailed to the other acute care institutions in Connecticut. How had state statutes and JCAHO requirements been interpreted regarding issues of medical staff rights and responsibilities, and the site and spectrum of surgery practice? What mechanisms had been used for credentialing, delineation of clinical privileges, and quality assurance? To what extent had traditional surgical specialties participated in these administrative activities? Can effective surgical quality assurance programs (with specific reference to podiatric surgery) be carried out in the outpatient setting? The data gathered might also prove useful if other nonmedical practitioners (chiropractors, naturopathic physicians, etc) apply for acute care hospital privileges in the future.

Methods

A questionnaire was sent to both the chief of surgery and quality assurance coordinator in each of the other 37 acute care hospitals in Connecticut including the two Veterans Administration Hospitals and the Newington Children's Hospital (Table 1). Through second mailings and follow-up telephone calls, a 100% institutional response was achieved. In addition to answering the questionnaire, many institutions expanded upon the issues raised, forwarding copies of their medical staff bylaws and the forms used for the delineation of clinical privileges in podiatry and podiatric surgery in their institution.

Results

The results of the survey (including New Britain General Hospital) are presented in Table II. While the

JOHN C. RUSSELL, M.D., Chief of Surgery and Program Director, New Britain General Hospital, New Britain, CT; Assistant Dean, Medical Education, Associate Professor and Associate Chairman, Department of Surgery, University of Connecticut School of Medicine, Farmington, CT.

Table 1
Podiatric Surgery Questionnaire

- 1) Do podiatrists have clinical privileges in your hospital?
Under what department?
- 2) If the podiatrists have surgical privileges (or if there is a subsection of podiatric surgery), what is the scope of surgical privileges and how were these privileges established?
- 3) Does your hospital require a probationary period (with mandatory supervision)?
- 4) Are podiatric surgeons subjected to a period of probation (with mandatory supervision)?
- 5) How is this probation conducted, and who provides the supervision?
- 6) Are orthopedic surgeons, general surgeons, or any other medical specialists involved in the process of supervision, credentialing, or delineation of clinical privileges (now or in the past) for podiatric surgeons?
- 7) How do you maintain Quality Assurance for podiatric surgery?

actual medical staff bylaws for each hospital were not requested or reviewed (unless sent by the institution), the questionnaire responses indicate that 25 hospitals already have granted clinical privileges to podiatrists. In the 13 remaining institutions, only five appear to have no provision for clinical privileges for podiatrists. However, the specific surgical privileges granted show a significant institutional variation.

Only 12 institutions give podiatrists full access to operating rooms and inpatient facilities. Seven of these institutions differentiate between podiatric generalists and individuals who have completed podiatric surgical residency training (or equivalent experience) by creating two to four levels of privileges within podiatry.

In the remaining 17 institutions in which the extent of podiatric privileges could be determined, the podiatrists are restricted to same-day, or outpatient surgical procedures (generally under local anesthesia only). Within the outpatient department, several institutions restrict the procedures to those which do not violate the joint capsule or the periosteum. Several institutions allow podiatrists only to provide bedside care to inpatients. One hospital requires board eligibility or board certification of applicants for podiatric surgical privileges, but then only allows the podiatrists to perform minor soft tissue procedures.

The responsibilities for credentialing, delineation of surgical privileges, probation, and quality assurance are usually assigned to the chief of surgery and/or chief of orthopedic surgery. Six hospitals, including the two VA hospitals, have established formal sections of podiatric surgery within the department of surgery or as a subsection of orthopedics, but usually with participation of general surgeons and/or orthopedists in the credentialing process. When probationary supervision is required, this is commonly a shared responsibility of the chief of surgery, chief of orthopedics, and podiatrists already on staff. In one Connecticut hospital, podiatry is considered for administrative purposes part of the outpatient department within the department of medicine.

JCAHO requires that the hospital-based quality assurance program must assure not only that surgery is carried out safely, but that the procedures performed are clinically indicated.¹ Many institutions do not appear to have addressed the issue of quality assurance for podiatric surgery. Others have assigned the responsibility for quality assurance for podiatric surgery to the chief of surgery or orthopedics in the context of monthly chart reviews, departmental morbidity and mortality conferences, or hospital-wide quality assurance screens. Presumably, the participation by medical specialists assures consistency in the approved indications for procedures for both podiatric surgeons and traditional surgical specialists, although it could not be determined whether podiatric surgeons have participated in a reciprocal fashion in the development of surgical procedure indications in the surgical specialties.

Discussion

Physicians and osteopaths licensed as general surgeons and orthopedic surgeons may privately decry the encroachment of a nonsurgical specialty, podiatric surgery, upon their traditional area of practice. However, the official position of the American Medical Association is that "...it recognizes the right of qualified limited practitioners, such as podiatrists and unlimited practitioners, such as doctors of medicine and osteopathy, to seek opportunities to utilize their knowledge and skills in hospitals and other health care facilities."² Even the American College of Surgeons has stated that "...licensed podiatrists may admit patients in collaboration with physicians responsible for the overall aspects of the patient care, must submit to overall supervision by the chief of the appropriate surgical service, and limit operative procedures to the foot and toes, with the type and extent of operative procedures to be determined by the Chief of Surgery upon the advice from the members of the surgical staff."³

In Connecticut, the scope of clinical practice in podiatry is defined as follows:

Podiatry is defined to be the diagnosis, prevention and treatment of foot ailments including the prescription, administering and dispensing of drugs and controlled substances in schedules II, III, IV, or V, in accordance with subsection d of section 21a-252, in connection therewith; the practice of surgery upon the feet, provided if an anesthetic other than a local anesthetic is required, such surgery shall be performed in a general hospital accredited by the Joint Commission on Accreditation of Hospitals by a licensed podiatrist who is accredited by the credentials committee of the medical staff of the said hospital, to perform podiatric surgery in conformance with the rules set forth by the chief of the surgical department of said hospital taking into account the training expertise, demonstrated competence and judgment of each licensed podiatrist and such podiatrists shall comply with such rules; the dressing, padding, and strapping of the feet; the

Table 2
Results of Questionnaire

1) Clinical privileges for podiatrists:		b) Department of surgery, Section of Podiatry:		6
a) Yes:	25	c) Department of Orthopedics,		
b) No:	13	Subsection of Podiatry:	13	
(1) Allowed by Bylaws, but none with active		d) Department of medicine (Outpatient):	1	
clinical privileges at this time:	8	e) Not stated:	1	
(2) No apparent provision:	5	5) Delineation of privileges/credentialing:		
2) Medical staff status:		a) Chief of surgery:	7	
a) Full medical staff:	11	b) Chief of orthopedics:	11	
b) Allied/adjunct staff:	11	c) Combined surgery/orthopedics:	6	
c) Consultant staff:	3	d) Combined orthopedics/podiatry:	2	
d) Other status:		e) Chief of podiatry:	1	
(1) Clinical privileges, but no membership on		f) Chief of OPD (medicine):	1	
medical staff:	1	g) Multidisciplinary medical staff committee:	1	
(2) Not specified:	9	h) Not stated:	4	
3) Scope of clinical privileges:		6) Probationary supervision:		
a) Full surgical privileges:	12	a) Chief/department of surgery:	9	
(1) One-tier:	5	b) Chief/department of orthopedics:	10	
(2) Two-tier:	5	c) Combined surgery/orthopedics:	2	
(3) Three-tier:	1	d) Combined orthopedics/podiatry:	1	
(4) Four-tier:	1	e) Chief of podiatry:	3	
b) Limited surgery:	17	f) Not stated:	4	
(1) Main OR (ambulatory surgery):	1	g) Not required:	4	
(2) Outpatient department/Emergency room/		7) Quality assurance program:		
bedside:	16	a) Chief of surgery:	7	
c) Not stated:	4	b) Chief of orthopedics:	10	
4) Departmental assignment:		c) Combined surgery/orthopedics:	1	
a) Department of surgery:	12	d) Chief of podiatry:	4	
		e) Chief of outpatient department (medicine):	1	
		f) "Being developed":	1	
		g) Not stated:	9	

the making of models of the feet and the palliative and mechanical treatment of functional and structural ailments of the feet, not including the amputation of the leg, foot or toes or the treatment of systemic diseases other than local manifestations in the foot.⁴

A recent court decision (State Medical Society versus Board of Examiners in Podiatry, 1988) has clarified the anatomic extent of podiatric practice by determining that "...the foot has a well accepted and common meaning that does not include the ankle."⁵

Podiatric surgery has emerged as a specialty within podiatry, paralleling the evolution of medical specialties. The American Board of Podiatric Surgery was founded in 1975 and is approved by the Council on Podiatric Medical Education of the American Podiatric Medical Association, the accrediting agency for podiatric medicine recognized by the United States Department of Education.⁶ Candidates for certification must have graduated from a four-year accredited college of podiatric medicine (five colleges in the United States); most podiatric medical students have previously completed baccalaureate degrees. Approved podiatric surgical residency programs are classified as either PSR-12 (12-month podiatric surgical residency) or PSR-24 (24-month podiatric surgical residency). As of 1980, approximately 128 hospitals provided residency programs; there were 342 first year places, 46 second year places, and one third year place.⁷

To receive board certification, a podiatrist must have completed an approved residency, have at least three years of documented case experience (50 cases for PSR-24 graduates, 75 cases for PSR-12 graduates) and successful completion of written and oral examinations.⁸ A lesser status of board eligibility is available for podiatrists who have completed a 24-month residency, or 12-month residency and written examination, while they are accumulating sufficient case material to meet the credentialing requirements for board certification. Until 1990, the requirement for residency training for both board-eligible or board-certified status can be waved in lieu of documented surgical case experience (75 cases). Also until 1990, there is a nonhospital category available for podiatrists who cannot obtain hospital privileges; in addition to submitting documentation of surgical cases, these podiatrists must undergo an on-site evaluation of the surgical facility (office or surgical center) where they perform their surgical procedures. Previously such individuals would qualify for certification by the American Board of Ambulatory Foot Surgery, which is now a section of the American Board of Podiatric Surgery.⁹

While acute care hospitals continue to be granted significant latitude by state statutes and judicial decisions in determining whether licensed podiatrists are granted clinical privileges, they must still abide by JCAHO guidelines.¹⁰ These standards include:

1) When privileges are granted to podiatrists, the medi-

cal staff bylaws, rules, and regulations must contain specific reference to podiatric services.

- 2) Podiatrists may write orders and prescribe medications within the limits of their licensure¹¹ and of the medical staff bylaws, rules, and regulations.
- 3) Admission of a podiatric patient shall be a *dual* responsibility of the responsible podiatrist and a physician member of the medical staff.
- 4) The podiatrist is responsible for that part of the history and physical that is related to podiatry. A physician member of the staff or a physician approved by the medical staff shall perform an admission history and physical examination, and record the findings in the medical record.
- 5) A physician member of the medical staff shall be responsible for the care of any medical problems that may be present on admission or that may arise during hospitalization of podiatric patients.

Similarly, JCAHO requirements for hospital-based quality assurance programs apply equally to limited practitioners, such as podiatrists, and unlimited practitioners, such as physicians and osteopaths.¹

Recognizing that hospitals may not have in-house expertise to evaluate properly requests for procedure-specific privileges, the American Podiatry Association recommends the use of consultants: "state podiatric societies, nationally renown podiatrists or specialty groups within the profession can provide the equivalent level of objective assistance."⁷ While the American Board of Podiatric Surgery does not define requirements for membership on any hospital staff,⁶ board certification, eligibility, or equivalent experience provide useful guidelines in the credentialing of podiatric surgeons.

Active podiatric surgical programs commonly include physicians to assist in the process of credentialing, privilege-delineation, supervision, and quality assurance. Podiatrists (specifically, podiatric surgeons) to date have not contested in court in Connecticut the involvement of physicians in these activities. One can argue that the joint involvement of podiatrists and physicians is mutually beneficial—physician involvement lends credibility to podiatric surgery among other medical specialists, while peer pressure from physicians may reduce the frequency of podiatric surgical procedures performed that conflict with traditional surgical indications.

Failure to allow podiatrists access to hospital-based resources, or failure to acknowledge the special training required for eligibility for certification in podiatric surgery in the credentialing and clinical privilege delineation process seem short-sighted and prone to accusations of

restraint of trade. Physician involvement in the establishment and administration of these programs affords the most realistic opportunities for quality control according to standards acceptable to both disciplines.

Recommendations

- 1) In establishing podiatric surgical programs, consider the use of consultative assistance in establishing guidelines for credentials, privilege delineation, probationary supervision, and quality assurance.
- 2) Develop procedure-specific privilege delineation that takes into account the various levels of training a podiatrist or podiatric surgeon may possess.
- 3) Involve appropriate medical specialists (general surgeons, orthopedic surgeons, physiatrists) in the administrative process.
- 4) Consider multidisciplinary involvement in the development of specific indications for surgical procedures that are *independent* of the specific disciplines doing the procedure (ie, there should be the *same* indications for a bunionectomy whether performed by an orthopedic surgeon or a podiatric surgeon).
- 5) State statutes, rather than the guidelines of state or national medical or podiatric professional organizations, should remain the final arbiters of the boundaries of clinical practice in podiatry and podiatric surgery, as well as other nonmedical disciplines.

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Cerebral Computed Tomography in a Stage IV Ethylene Glycol Intoxication

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ABSTRACT—The findings on cerebral computed tomography (CT) are correlated with Stage IV ethylene glycol syndrome. Central nervous system anoxia produced by the by-products of ethylene glycol is proposed as the culprit for the severe cerebral edema evidenced in Stage IV.

Introduction

ETHYLENE glycol intoxication results in a severe metabolic acidosis with an increased anion gap. Once ingested, ethylene glycol is rapidly absorbed and distributed throughout the body tissue. Along the metabolic pathways the ethylene glycol, oxalic acid, hippuric acid, glycolic acid, and formic acid are formed. While the metabolic acidosis is due primarily to the glycolic acid,¹ the renal convoluted tubules (less so in the collecting tubules) and the brain tissues show deposits of oxalate crystals.

A fairly typical clinical syndrome has been described in ethylene glycol intoxication. This syndrome typically consists of three stages,^{2,3} but a fourth stage has been proposed by Factor and Lava.⁴ While stage I represents early central nervous system (CNS) involvement, stage IV also involves the CNS, but occurs days after the intoxication. Maier reported the cerebral changes found in the computed tomography (CT) in ethylene glycol intoxication,⁵ but no correlation with this clinical stage IV was made.

This report concerns the CT appearance in a patient during the fourth stage ethylene glycol intoxication.

Case Report

A 33-year-old caucasian woman with the history of a premorbid personality disorder had threatened to ingest antifreeze in the evening prior to her admission. She was brought to the emergency room after her mother found her comatose in bed in the morning. A physical examination showed her unresponsive to pain and pressure, and with reduced deep tendon reflex responses. There was no

rash and no evidence of head trauma, and her neck was supple. Her lungs were clear and the heart revealed no murmur or gallop. The pupils measured 3 mm bilaterally and reacted to light. The optic disks were normal. Laboratory studies showed a pH of 6.8 and bicarbonate of 2.9 mEq/L. The serum urea nitrogen was 14 mg% and the creatinine was 3.9 mg%. She had an anion gap of 37 mEq/L and an osmolar gap of 3. Initial treatment consisted of gastric aspiration, oral administration of activated charcoal, and infusion of sodium bicarbonate. A urinalysis showed calcium oxalate crystals. Ethanol, salicylate, and acetaminophen levels were negative. The plasma ethylene glycol level (12 hours after ingestion) was 187 mg%. Dialysis treatment was then started and continued for three hours. A repeat ethylene glycol level was negative after dialysis. The CT performed at admission showed that there was no intra- or extra-axial fluid collection and the ventricular and cortical sulci appeared normal.

The patient's neurologic status improved but renal failure developed necessitating intermittent hemodialysis.

On the 10th day after ingestion of the ethylene glycol, the patient gradually became hypertensive with a blood pressure 180/120 mm Hg. Despite hemodialysis and antihypertensive medications, her hypertension did not improve. On the 11th hospital day the patient again became comatose. Her pupils measured 1 mm and were sluggishly reactive. The optic disks showed papilledema. Cranial nerve examination demonstrated facial diplegia. The chest film showed pleural effusion. CT was performed and showed marked edema and leukoencephalopathy of both hemispheres; the low density areas did not conform to any specific vascular territories. The CT finding conformed to a toxic or inflammatory encephalopathy rather than infarction. When intracerebral pressure (ICP) monitoring was instituted, her initial ICP was 30-35 mm Hg. With hyperventilatory and steroidal treatments, her ICP was maintained within normal limits of 10-15 mm Hg.

During the next 20 days, her renal and neurological sequelae improved. Although her cerebral edema shown

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in CT decreased drastically, the patient developed some residual temporal lobe dysfunctions and auditory verbal agnosia.

Discussion

Four different stages of ethylene glycol poisoning have been described according to the predominant symptoms and the time after ingestion of the agent:⁴

- I. Early cerebral phase,
- II. Cardiopulmonary phase,
- III. Renal phase,
- IV. Late cerebral phase.

Stage I occurs between 30 minutes and 12 hours after ingestion and involves mainly the CNS. Fatigue, headache, and confusion are the main complaints, but with large overdoses of ethylene glycol, convulsion and coma may develop quickly.

Stage II occurs 12-24 hours after ingestion and is represented by pulmonary and cardiac failure. Typically, tachycardia, tachypnea, and hypertension develop.

Stage III occurs 24-72 hours after ingestion and it can be recognized by loin pain and increasing renal failure. The oliguria may actually last as long as 50 days;³ however a return to normal is to be expected.

Stage IV occurs six to 13 days after ingestions and involves the CNS. Neurological sequelae include facial diplegia, anisocoria, dysphagia, hyperreflexia, and elevated cerebrospinal fluid protein.

On the other hand, Pons reported that approximately 50% of the 18 lethal cases of ethylene glycol poisoning examined at autopsy had cerebral edema and meningoencephalitis reactions.⁶ These represented the stage I CNS depression which corresponded with the CT reported by Maier.⁵

The CT findings in our case are different from those reported earlier by other authors. The stage I CT was shown to be within normal limits, whereas the CT performed in stage IV revealed severe cerebral edema.

After the ethylene glycol poisoning, glycolaldehyde

accumulates in the CNS and decreases cellular aerobic respiration causing CNS anoxia and cerebral edema by a mechanism akin to the ischemic cell swelling event.⁷ This may be the causative mechanism of a late CNS injury as represented by stage IV where the cerebral CT showed severe edema. It is interesting that in our case, the patient's blood pressure became dangerously high and unresponsive to antihypertensive therapy 12 hours prior to her full-blown picture of stage IV. The neurologic sequelae of temporal dysfunction is consistent with the preferential injury of the hippocampus by hypoxia⁴ and/or injuries similar to the earliest meningoencephalitis.

With the advent of better diagnosis and treatment, most patients survive acute ethylene glycol poisoning and Stage IV of the ethylene glycol syndrome will occur with increasing frequency. However, the reciprocal decline in autopsy in this poisoning limits our opportunities to analyze the correlation between various clinical stages, pathological appearances, and cerebral CT scans. Moreover, the variable expressions of the syndrome, as shown in the reported cases in literature, create another obstacle to the understanding of the pathogenesis of this syndrome. The authors hope this paper will help to bring to light the work ahead in explaining the early and late CNS signs and symptoms in ethylene glycol poisoning.

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AIDS Related Testing and Confidentiality: Connecticut's New Legislation

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EFFECTIVE 1 October 1989, Connecticut joins a growing number of states which have adopted legislation governing confidentiality and consent issues relating to AIDS.¹ The Connecticut law, entitled "An Act Concerning AIDS Related Testing and Medical Information and Confidentiality," Public Act No. 89-246, was signed by Governor O'Neill on 22 June 1989. The new law clarifies many uncertainties which have existed in the areas of informed consent, disclosure of confidential information, and the possible duty to warn infected partners. This article will highlight and summarize provisions of this lengthy statute that are likely to be of greatest interest to physicians.

The specific rights and requirements set forth in Connecticut's new legislation will supercede and take precedence over any conflicting guidelines, interpretations, and advice that have been provided previously by private and public associations and agencies regarding matters covered by the Act.

The Connecticut Department of Health Services (the "Department") is authorized by the Act to promulgate regulations implementing certain provisions of the Act, and the Department is required to develop a recommended consent form for HIV related testing as discussed below. However, the Act provides no role for the Department in enforcing these requirements. The only express provision for enforcement of the Act is a private right of action for willful violation of any provision of the Act as set forth in Section 10.²

HIV Testing - Informed Consent and Pre and Posttest Information and Counseling Requirements

Informed Consent

Section 2(a) of the Act imposes specific requirements regarding HIV related testing on the "person who orders

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¹For a survey of AIDS related legislation in other states, see Gostin L.O.: Public Health Strategies for Confronting AIDS. *JAMA* 1989, 261: 1621-9.

²Section 10 of the Act provides: Any person, except as otherwise provided in this act, who wilfully violates any provision of this act shall be liable in a private cause of action for injury suffered as a result of such violation. Upon a finding that an individual has been injured as a result of such violation, damages shall be assessed in the amount sufficient to compensate said individual for such injury.

performance of the test," which generally will be the physician. Section 2(a) provides, with limited exceptions, that *no person shall order the performance of an HIV related test without first receiving written informed consent, or oral informed consent which has been documented in the medical record*, of the subject of the test or of a person authorized to consent to health care for such individual.³ The law states that whenever practicable, written consent must be obtained.⁴

The Act (§2(a)) further provides that the person ordering the performance of the HIV related test must certify that informed consent has been received prior to ordering testing, and laboratories are prohibited from performing the tests without written certification that (1) consent has been obtained or (2) a statutory exception to the consent requirement applies.

The Act contains a lengthy and detailed listing of elements that must be included in a statement provided in obtaining informed consent to an HIV related test.⁵ The Department of Health Services is required by the Act to develop recommended forms for use in documenting informed consent. The Department is already working on the form and anticipates that it will be available before 1 October 1989, when the Act becomes effective.

Use of the Department-approved written consent form

³The Act does not specify who may be authorized to consent to health care for another individual, and general rules regarding consent by conservators or guardians and other substituted consent should therefore be followed.

⁴The Act (§2(f)) provides that informed consent shall be obtained for each HIV test, or in the case where a sequence of tests is required to confirm an initial positive result, for each sequence of tests.

⁵Pursuant to §2(b) of the Act, informed consent to an HIV related test shall include a statement of at least the following: (1) an explanation of the test, including its purpose, the meaning of its results, and the benefits of early diagnosis and medical intervention; (2) acknowledgment that consent to an HIV test is not a precondition to receiving health care but that refusal to consent may, in some circumstances, affect the provider's ability to diagnose and treat the illness; (3) an explanation of the procedures to be followed, including that the test is voluntary, and a statement advising the subject on the availability of anonymous testing; and (4) an explanation of the confidentiality protections afforded confidential HIV related information including the circumstances under which and classes of persons to whom disclosure of such information may be required, authorized, or permitted by law. Such explanation shall specifically acknowledge that known partners of the protected individual may be warned of their potential risk of infection without identifying the protected individual and that the law permits the recording of HIV and AIDS related information in medical charts and records.

would generally seem to be the simplest and most conservative way of documenting that the statutory consent requirement has been met. The signed form should be part of the patient's medical record.

Pretest Information and Posttest Counseling or Referral

Section 2(c) of the Act contains a pretest information requirement. This section provides that prior to obtaining informed consent, a person ordering the performance of an HIV related test shall provide the subject or person authorizing consent with "an explanation of the nature of AIDS and HIV related illness and information about behaviors known to pose risks for transmission of HIV infection." Although the Act does not state that the person ordering the test must provide this information in person and the physician thus may have assistance from an employee or agent, the physician ordering the test will have ultimate responsibility for providing of the pretest information.

Section 2(d) of the Act contains a posttest counseling or referral requirement. This provision states that at the time of communicating the test results, the person ordering the performance of an HIV related test shall provide the subject (or person authorized to consent to health care for the subject) with counseling or referrals for counseling: "(1) for coping with the emotional consequences of learning the result; (2) regarding the discrimination problems that disclosure of the result could cause; (3) for behavior change to prevent transmission or contraction of HIV infection; (4) to inform such person of available medical treatments; (5) regarding the need of the test subject to notify his partners and, as appropriate, provide assistance or referrals for assistance in notifying partners." It should be noted that the Act expressly allows physicians to refer patients to another source for posttest counseling. Physicians who order HIV tests may wish to explore the willingness of local AIDS organizations to accept such referrals.

In addition to documenting the obtaining of informed consent, physicians should develop means for documenting in the medical record compliance with pretest information and posttest counseling or referral requirements. The Department is mandated by the Act to develop guidelines for providing such explanations.⁶

Test Results

Laboratories are required to report test results to the person who orders performance of the test (§2(a)). Although a patient may refuse to receive his test result, the Act (§2(d)) provides that the health care provider may not withhold test results and states that the person ordering the performance of the test shall encourage the

patient to receive the result and to adopt behavior changes that will allow him to protect himself and others from infection.

Exceptions

Section 2(e) outlines several narrow and specific exceptions to the consent and/or pretest information and posttest counseling requirements, such as: (a) in situations in which the subject is unable to give consent, no other person is available who can give consent, and test results are needed in order to provide urgent care; (b) in circumstances relating to procurement and use of human organs for research or transplantation; (c) for research, if the identity of the subject is not known; (d) for testing on a deceased person when such test is conducted to determine the cause or circumstances of death or for epidemiological purposes; (e) in certain circumstances regarding correctional facilities; (f) pursuant to appropriate court orders; or (g) when the test is conducted by any health or life insurer for determining coverage. As discussed below, another exception to the consent requirement may apply in certain circumstances where a health care provider or other person in the course of his occupational duties has had a "significant exposure" to possible HIV infection.

HIV Testing - A Summary Checklist

In order to comply with the Act's requirements for HIV testing, regardless of whether the patient requests testing or the physician first recommends the test, the following checklist should be applied.

1. The physician must provide a pretest explanation of the nature of AIDS and HIV related illness and information about high-risk behaviors (§2(c)), and should document in the record that such explanation and information have been provided.
2. The physician must obtain informed consent to the testing from the patient (or from a person authorized to consent to health care for the patient), as documented by a signature on the Department's approved consent form (or a carefully drafted substitute). When written consent is not practicable, oral informed consent should be documented in detail in the medical record (§2(a)).
3. The physician must certify in writing to the laboratory that informed consent has been obtained or that one of the statutory exceptions to the consent requirement applies (§2(a)).
4. The physician may not withhold test results and must encourage the patient to receive his test results and to adopt behavior changes to protect himself and others from infection (§2(d)). Such discussions should be documented in the medical record as appropriate.
5. When communicating the test result, the physician must provide the patient (or the person authorized to consent to health care for the patient) with counseling or referrals for counseling regarding coping with the emotional consequences of the

⁶The Act (§2(a)) requires that any form used for informed consent and all information conveyed in pretest and posttest discussions must be conveyed in a clear and coherent manner using plain language as described in Section 42-152 of the Connecticut General Statutes. The Act (§2(a)) expressly states that a person ordering the performance of an HIV related test shall not be held liable if a good faith effort is made to convey the explanations required in obtaining informed consent and in pretest and posttest information and counseling or referral.

result, the potential for discrimination, appropriate behavior changes, available medical treatments, and the need and means to notify partners (§2(d)). The physician should document compliance with the counseling or referral requirement in the patient's medical record.

Management of "Significant Exposures"

Since health care providers began to encounter patients with AIDS and HIV on a regular basis, many questions have been raised regarding the handling of accidental exposures of health care workers to potential HIV infection. Such questions include when the source patient can be tested for HIV and whether test results can be disclosed to the exposed health care worker. The new Connecticut legislation specifically addresses management of "significant exposures."⁷ In the event of a "significant exposure" that occurs in the course of occupational duties, detailed exceptions to both the informed consent requirement and the confidentiality provisions of the Act may apply (§§2(e)(5), 3(a)(7)).

Testing of the source patient without informed consent and disclosure of test results to the exposed health care worker will be permitted if all of the specific criteria set forth in the Act are satisfied: (A) the worker is able to document significant exposure during performance of his occupation; (B) the worker completes an incident report within 48 hours of exposure identifying the parties to the exposure, witnesses, time, place, and nature of the event; (C) the worker submits to a baseline HIV test within 72 hours of the exposure and is negative on that test; (D) the patient has been asked to consent voluntarily to HIV testing and disclosure of results and has refused such consent (except when the patient is deceased); (E) an "exposure evaluation group," consisting of at least three impartial health care providers, including at least one physician, determines that the above criteria have been met and that a "significant exposure" has occurred; and (F) the worker would be able to take "meaningful immediate action" if test results are known, which could not otherwise be taken, as defined in regulations adopted by the Department of Health Services.⁸

If the criteria listed above have been satisfied, a sample of the patient's blood may be tested by a health care

facility caring for the patient, or if no sample of blood is available, a patient under the care or custody of a health care facility shall have a blood sample drawn.⁹ If the patient is not under the care of a health care facility or other institution and a physician not directly involved in the exposure certifies that the relevant criteria have been met, the health care worker may seek a court order for testing. If the criteria have been met, results of the HIV test may be disclosed to the exposed health care worker without need for a court order.¹⁰

Disclosure of HIV Related Information

Section 3 of the Act provides that no person who obtains "confidential HIV related information" may disclose such information, with several limited exceptions outlined below.¹¹

One of the exceptions permits confidential HIV related information to be disclosed to the "protected individual" (ie, the patient) or his legal guardian.^{12,13}

Confidential HIV related information also may be disclosed to any person who secures a written release authorizing disclosure which complies with the Act's specific requirements.¹⁴ Disclosure also is permitted for reports to federal, state, or local health officers which are mandated or authorized by federal or state law.

With respect to communications among health care providers, disclosure of HIV related information is permitted when necessary to provide appropriate care or

⁹The Act (§2(e)(5)(G)) provides that the fact that an HIV test was given as a result of an accidental exposure and the results of that test shall not appear in a patient's medical or other record held by an institution unless such test result is relevant to the patient's medical care. The Act (§2(e)(5)(H)) further provides that posttest counseling shall be provided, but the patient may choose not to be informed about the result of the test.

¹⁰The management of significant exposures is addressed in proposed regulations of the Occupational Safety and Health Administration (OSHA) which were published in the Federal Register on May 30, 1989, 54 Fed. Reg. 23042 *et seq.* If final regulations of OSHA conflict with the requirements of the Connecticut legislation, the interrelationship of these requirements will need to be reviewed carefully.

¹¹"Confidential HIV related information" is defined in the Act (§1(8)) as: Any information pertaining to the protected individual or obtained pursuant to a release of confidential HIV related information, concerning whether a person has been counseled regarding HIV infection, has been a subject of an HIV related test, or has HIV infection, HIV related illness or AIDS, or information which identifies or reasonably could identify a person as having one or more of such conditions, including information pertaining to such individual's partners.

¹²"Protected individual" is defined as "a person who has been counseled regarding HIV infection, is the subject of an HIV related test or who has been diagnosed as having HIV infection, AIDS, or HIV related illness" (§1(7)).

¹³It could be inferred from the posttest counseling provision, §2(d) of the Act, that results of the HIV test will be disclosed to the "person authorized to consent to health care for the subject," who may be someone other than the "legal guardian." This potential inconsistency in the Act could be provided for by including in the informed consent form a provision authorizing disclosure of results to the person giving consent.

¹⁴To comply with the Act (§1(9)), a written authorization for disclosure of confidential HIV related information must be signed by the protected individual or by a person authorized to consent to health care for the individual, be dated, and specify to whom disclosure is authorized, the purpose of such disclosure, and the time period during which the release is to be effective. A general authorization for the release of medical information will not authorize release of HIV related information unless it includes all of the required elements and specifically indicates its dual purpose.

⁷The Act (§1(14)) defines "significant exposure" as "a parenteral exposure such as a needlestick or cut, or mucous membrane exposure such as a splash to the eye or mouth, to blood or a cutaneous exposure involving large amounts of blood or prolonged contact with blood, especially when the exposed skin is chapped, abraded, or afflicted with dermatitis." The Department of Health Services may choose to define "significant exposure" further by regulation.

⁸An example of a "meaningful immediate action" would be the opportunity for immediate treatment with AZT or other drugs. Regulations defining "meaningful immediate action" will probably not be published before 1 October 1989, and a question has been raised regarding the effect of the Act's "significant exposure" provisions without such regulations. Although the Department has taken a preliminary position that these provisions will not be effective absent the defining regulation, persons responsible for management of a "significant exposure" prior to promulgation of the regulations should consult their own legal counsel.

treatment to the protected individual or to a child of the individual. In addition, disclosure is permitted when the confidential information is already recorded in a medical chart or record and the health care provider has access to such record for the purpose of providing medical care to the protected individual.

A further exception to the confidentiality requirement permits disclosure of HIV related information to a medical examiner to assist in determining the cause or circumstances of death. Health facility staff committees or accreditation or oversight review organizations may have access to confidential HIV related information in conducting program monitoring, program evaluation, or service reviews. Other exceptions permit disclosure under special circumstances in State hospitals for mental illness and in Department of Corrections facilities.

Disclosure of confidential HIV information is permitted to life and health insurers, government payers, and health care centers and their affiliates in connection with underwriting and claim activity for life, health, and disability benefits. As discussed above, a further exception allows disclosure to a health care worker who has had a "significant exposure" to HIV infection when criteria specified in the Act have been met. In appropriate circumstances, disclosure may be permitted by a court order.¹⁵

No person to whom confidential HIV related information is disclosed, except the protected individual or his legal guardian, may further disclose such information except as provided by the Act (§3(b)).

When HIV related information is disclosed in accordance with an exception to the Act's confidentiality requirement, such information must be accompanied by a statement, which is in writing whenever possible, and which includes statutory language regarding the protected nature of the information and prohibitions on further disclosure (§5(a)). An oral disclosure must be accompanied or followed by such a notice within 10 days. With certain exceptions specified in the Act, a notation of all disclosures shall be placed in the medical record or with any record of an HIV related test result, and the protected individual upon request shall be informed of the disclosures (§5(b)).¹⁶

It should be noted that the Act expressly allows the recording of HIV and AIDS related information in the patient's medical record and the listing of AIDS, HIV related illness, or HIV infection in a death certificate or autopsy report (§5(e)).

¹⁵A subpoena issued by an attorney does not authorize disclosure of confidential HIV information. A physician served with a subpoena seeking such information should consult legal counsel.

¹⁶Neither the requirement for providing notice of the prohibitions on redisclosure nor the requirement for noting disclosure in the medical record applies to disclosures to life and health insurers, government payers, and health care centers made in connection with underwriting and claim activity for life, health, and disability benefits (§5(d)).

Notification of Partners Regarding Exposure to HIV

A particularly difficult question in recent years regarding AIDS and HIV has been whether physicians are permitted or have a duty to warn known partners of a patient regarding possible exposure. Section 4 of the Act expressly addresses this concern. As described below, this section clarifies the procedures that may be followed in informing known partners and expressly provides that the physician shall have no obligation to warn or inform, identify, or locate any partner and no obligation to disclose information to a public health officer for purposes of warning or informing a partner.

The new Act generally assigns the task of warning "partners" in appropriate circumstances to a public health officer who is an employee of the Department of Health Services.¹⁷ Under the circumstances outlined below, however, a physician has the option of disclosing HIV related information directly to a known partner if both the protected individual and the partner are under the physician's care.

Pursuant to section 4(b), a physician may disclose confidential HIV related information to a known partner of a protected individual if both the partner and the protected individual are under the physician's care or to a public health officer for the purpose of informing or warning partners of the protected individual that they may have been exposed to the HIV virus under the following conditions: (1) the physician reasonably believes there is a significant risk of transmission to the partner; (2) the physician has counseled the protected individual regarding the need to notify the partner and the physician reasonably believes the protected individual will not inform the partner; and (3) the physician has informed the protected individual of his intent to make such disclosure to the partner or public health officer.

The physician may also warn or inform a partner at the request of a protected individual, but is not required to do so. When making the disclosure to the partner, the physician shall provide or make referrals for the provision of the appropriate medical advice and counseling.

When disclosing information to a partner, the physician or public health officer shall not disclose the identity of the protected individual or the identity of any other partner. It also appears that in disclosing the names of known partners to the public health officer, a physician may not disclose the name of the protected individual (ie, the patient).

The Act (§4(b)) requires the public health officer or physician making a notification to make the disclosure in person whenever possible. When requested by a physi-

¹⁷The Act (§1(10)) defines "partner" as "an identified spouse or sex partner of the protected individual or a person identified as having shared hypodermic needles or syringes with the protected individual."

cian, the public health officer shall make a good faith effort to notify the partner of the risk of HIV infection. The law is very clear, however, that neither the physician nor the public health officer have any legal obligation to warn or inform, identify or locate any partner and, as stated above, that the physician has no obligation to disclose information to a public health officer for the purpose of warning or informing a partner.¹⁸

Conclusion

The intent of this article has been to inform physicians of the basic general requirements and provisions of Connecticut Public Act No. 89-246. It is important to note that each section of the Act has detailed provisions which might be relevant in a specific case. Questions of interpretation and legislative intent are likely to arise as the Act is applied to real situations. Physicians should be aware of forms, guidelines, and regulations as they are

issued by the Department of Health Services and should raise any questions of interpretation which arise with the Connecticut State Medical Society and/or with legal counsel.

¹⁸The Connecticut Act's approach for warning or informing known partners is essentially consistent with the Report of the American Medical Association Council on Ethical and Judicial Affairs dated 13 November 1987 which recommended that when there is no statute that mandates or prohibits the reporting of seropositive individuals to public health authorities and a physician knows that a seropositive individual is endangering a third party, the physician should: (1) attempt to persuade the infected patient to cease endangering the third party; (2) if persuasion fails, notify authorities; and (3) if the authorities take no action, notify the endangered third party. Pursuant to the new Connecticut legislation, however, physicians in Connecticut may directly warn endangered third parties only when the patient has specifically requested that the physician inform the partner or when both the partner and the protected individual are under the care of the physician.

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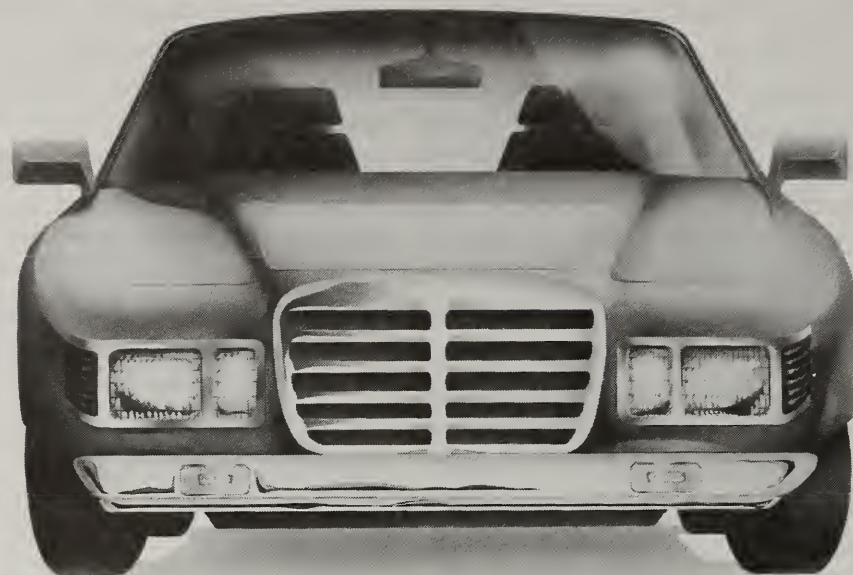
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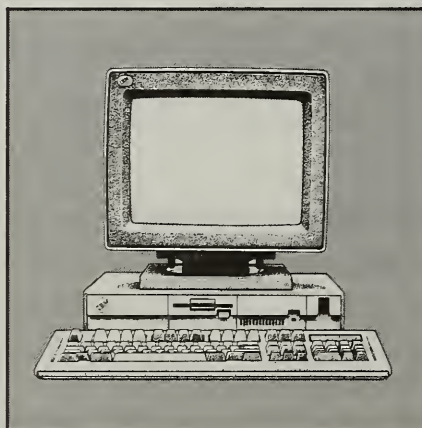
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Abstracts by Residents and Fellows

NEWINGTON CHILDREN'S HOSPITAL

FORWARD: The abstracts below are of papers presented at The Newington Children's Hospital Orthopaedic Resident Presentation Day in December of 1988. Orthopaedic residents spend six consecutive months at Newington Children's Hospital. Currently there are six residents at Newington from Yale University, the University of Connecticut, and Dartmouth Medical Center. While at Newington, each resident is required to produce an original research paper. These projects are supported by the Newington Senior Orthopaedic Faculty, and all necessary research funds are obtained through a Newington Children's Hospital grant. From the twelve papers generated each year, four or five are selected for presentation at the Newington Children's Orthopaedic Conference held each October. The majority of these papers go on to presentation at national meetings and are also developed for eventual publication. As of this writing, the paper by Drs. Federico and Renshaw will be presented at the Scoliosis Research Society Meeting in September 1989 in Amsterdam, the Netherlands.

Peter A. DeLuca, M.D., Director, Hip and Foot Service, Newington Children's Hospital, Newington.

The Charleston (Night Time) Bending Orthosis Treatment for Idiopathic Scoliosis

DALE FEDERICO, M.D. AND THOMAS S. RENSHAW, M.D.

This is a preliminary report evaluating the use of the Charleston Bending Orthosis at Newington Children's Hospital. This night-time orthosis treats a scoliotic curve by reversing the lateral bend during its use. No published data are available.

We evaluated 23 patients who met the following criteria: 1) a single structural curve of greater than 25° with evidence of progression (ie, greater than 5° in six months), 2) a curve apex caudal to the T⁷ level, 3) skeletal imma-

turity (ie, Risser stage less than 2), 4) full compliance, and 5) orthotic treatment for at least ten months.

At treatment initiation the average patient's age was 12.1 years and the average curve magnitude was 29.3°. Seven patients reached skeletal maturity and in all seven curve progression was halted (28.7° at onset and 25.4° at maturity). Twenty-two of the 23 patients showed a decrease or maintenance of curve magnitude for thoracic, thoracolumbar, and lumbar curves. One patient failed treatment despite compliant use. The Charleston Bending Orthosis appears to be effective in treating single curves in this preliminary study, providing the above criteria are met.

DALE FEDERICO, M.D., Orthopaedic Resident, Yale University School of Medicine, New Haven. THOMAS S. RENSHAW, M.D., Faculty Sponsor, Newington Children's Hospital, Newington.

Kinetics and Kinematics of Gait in Patients with Unilateral Hip Fusion

PETER MASSO, M.D. AND GREGORY MENCIO, M.D.

Five patients post hip fusion were evaluated at Newington Children's Hospital using clinical and radiographic examinations as well as kinetic and kinematic data from gait analysis. All patients were males. Two had a fusion for the sequelae of a septic joint, two for slipped capital femoral epiphysis with chondrolysis or avascular necrosis, and one was a patient with arthritis following Legg-Perthes disease. Four of the five patients had a right hip fusion. The average age at fusion was 14.6 years (range 10.7 to 17.7); the mean follow-up period was 29.5 years (range 17.7 to 45.5) with the average duration of fusion being 14.9 years (range 3.8 to 28.3). Three of the five patients had a full level of activity with participation in sporting activities; two patients had a more sedentary life style. One patient complained of knee pain and one of knee instability.

Gait analysis showed a shorter single stance time for

the fused limb and a longer single stance time for the nonfused limb (39% vs 45% respectively) with corresponding changes in stride length. The pelvis showed a marked increase in sagittal plane motion (14° vs 3°), a hip hike pattern in the coronal plane (for clearance of the foot in swing), and a slight increase in pelvic rotation in the transverse plane (to increase stride length). Sagittal plane hip motion was increased on the nonfused side as well as the power generated at that hip. Sagittal plane knee motion was abnormal on the fused limb with a progressive flexion throughout stance with a prolonged flexor moment (with the lack of quadriceps function). Transverse plane motion at the knee was markedly increased on the fused side and mildly increased on the nonfused side (to compensate for the lack of rotation at the hip which strains the ligaments about the knee). Ankle motion was characterized by an equinus position (to compensate for the length discrepancy) with a vaulting response to aid in clearance.

A prospective study will be performed to assess lower extremity joint stresses following hip fusion.

PETER MASSO, M.D., Orthopaedic Resident, University of Connecticut School of Medicine, Farmington. GREGORY MENCIO, M.D., Faculty Sponsor, Newington Children's Hospital, Newington.

Analysis of the Salter Osteotomy for the Treatment of Congenital Hip Dysplasia

TIMOTHY MCGOWEN, M.D. AND PETER A. DELUCA, M.D.

A retrospective review of 43 Salter osteotomies performed in 39 patients was undertaken to determine the outcomes and identify patients at risk for complications. All grades of idiopathic hip dysplasia were included except those with preexisting avascular necrosis. The mean follow-up period was 10.2 years. Treatment failure occurred in 10 patients (23%) and included one redislocation

and nine cases of recurrent subluxation. Two patients developed avascular necrosis. Nine patients required additional surgery. In general, patients fulfilling the preoperative criteria outlined by Salter had lower complication rates. Failure to achieve adequate reduction preoperatively was the most frequent cause of failure. Open reduction performed with the innominate osteotomy had the highest complication rate suggesting that combining the procedures simultaneously increases the risk of recurrent subluxation and/or dislocation.

TIMOTHY MCGOWEN, M.D., Orthopaedic Resident, Yale University School of Medicine, New Haven. PETER A. DELUCA, M.D., Faculty Sponsor, Newington Children's Hospital, Newington.

Reduction of Homologous Blood Transfusions in Spinal Fusion Surgery

PABLO VASQUEZ—SEONE, M.D. AND THOMAS S. RENSHAW, M.D.

In 1986, 20 consecutive patients undergoing spinal fusion surgery for the correction of idiopathic scoliosis had an average blood loss per patient of 1,247 cc. These 20 patients required a total of 49 units of homologous blood transfusion, an average of 2.45 units per patient. In 1988, a similar group of 20 consecutive patients had an average blood loss per patient of 1,256 cc. All of these patients had intraoperative blood salvage and retransfusion utilizing a cell saver and 13 of the patients participated in an autologous blood predonation program and received a total of 32 units of autologous blood. In this group of 20 patients, only three units of homologous

blood were required, an average of 0.15 units per patient.

In 1986, 10 consecutive patients who underwent corrective spinal surgery for neuromuscular scoliosis had an average blood loss of 1,490 cc. Thirty-nine units of homologous blood, an average of 3.9 units per patient, were necessary for transfusion. In 1988, a similar group of 10 consecutive patients had an average blood loss per patient of 1,828 cc. This group all had intraoperative blood salvage and retransfusion of an average of 814 cc per patient (44.5%). This group required 20 units of homologous blood transfusion, an average of two units per patient.

It appears that the use of autologous blood predonation and intraoperative blood salvage and retransfusion can provide a dramatic reduction in the need for the transfusion of banked homologous blood in spinal surgery.

PABLO VASQUEZ—SEONE, M.D., Orthopaedic Resident, Yale University School of Medicine, New Haven. THOMAS S. RENSHAW, M.D., Faculty Sponsor, Newington Children's Hospital, Newington.

Scoliosis and Hip Instability in Myelodysplasia

CHRISTOPHER WALTON, M.D. AND JOHN V. BANTA, M.D.

The purpose of this study was to examine retrospectively the incidence and the relationship of scoliosis and hip instability in 71 patients with myelomeningocele who were followed at Newington Children's Hospital. The minimum age was 10 years, the minimum follow-up was two years, and all patients had been evaluated within the past two years. Fifty-eight percent of the patients developed scoliosis and 45% developed hip instability. Seventy-five percent of the scoliotic deformities were right-sided;

the distribution of hip instability was equal. Patients with thoracic lesions were as likely to have hip instability as those with an L3-L4 lesions. In contrast, patients with thoracic lesions had a 95% incidence of scoliosis while the patients with L3-L4 lesions had a 50% incidence.

A temporal relationship between increasing hip instability and scoliosis was not demonstrated. The factors that correlated most closely with progressive scoliosis were size of the curve at age 10, the motor level of muscle paralysis, and the most distal intact laminar arch. We concluded that neuromuscular imbalance rather than hip stability is the primary factor in progression of spinal deformity in this group of patients.

CHRISTOPHER WALTON, M.D., Orthopaedic Resident, Dartmouth School of Medicine, Hanover, N.H. JOHN V. BANTA, M.D., Faculty Sponsor, Newington Children's Hospital, Newington.

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Being an Academic Surgeon*

BARBARA K. KINDER, M.D.

THE choice of this topic for my presidential address to the Connecticut Society of American Board Surgeons has several origins. First, we are in the company of a number of surgical residents who have shown us very well today what being an academic surgeon is in part about: that is, asking a question about an observed phenomenon, devising methods to answer the question, collecting and analyzing the data, and formulating conclusions based on the data. I wanted in part to bear tribute to their activity. Secondly, I thought it might be interesting to some of you who have chosen a different focus to your careers to learn why at least this surgeon has chosen to throw her lot with the academic community, instead of getting, as my parents might say, a "real job." And mostly, I suppose this choice gave me the excuse to reexamine my own thoughts at the midpoint of my career, a time point that has been identified as critical for many academic surgeons in determining whether or not they stay "in the fold."

First, I suppose I should make some attempt to define "academic surgeon." All surgeons should, perhaps more importantly than other physicians and despite our characterization as a noncognitive specialty, be academic in the sense of being critical thinkers and thoughtful proponents of our craft. However, I am defining academic as including not only the commitment to excellent clinical surgery and the enjoyment of teaching and learning from medical students and house officers which we all share, but also requiring the desire, indeed, the passion, to do research. I see the three components interacting somewhat as follows (Figure 1):

Teaching and patient care are large congruent circles. They are mutually dependent. Excellence in surgical skills is fundamental to this interaction. As Dallas Phemister said, "*One cannot teach well what he does not do well.*"¹ I also believe that patient care is equally dependent on teaching. Excellent care requires a skilled team effort with all members of the health care team continually educating one another as technical and societal

trends will continue to outstrip the ability of any of us as individuals to cover all the bases.

By teaching, I mean to include more than just talking about what we're doing to the resident while we're doing it. That is, of course, the basic currency of clinical education, but we need to be able to think creatively about new ways to stimulate and facilitate learning in our students and residents. We may need some help from other educators. After all, most of us were not really taught how to teach, we just wing it and count on the validity of the preceptor model of medical education and aptitude of our residents to accomplish the transfer of surgical judgment and skill from us to them. Perhaps too often, under the pressure of clinical surgery, the answer to the resident's question is "we see this." Such episodes should at least serve as stimuli to explore the issue at hand when the crisis has been averted. We need to give more critical thought to the processes of teaching and learning and we need to have as a priority the training of our residents to be good teachers themselves.

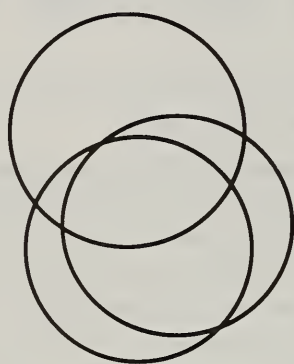
You'll notice that the research circle stands in a somewhat different relationship to the others. From my perspective, there is a substantial overlap with patient care and teaching. A basic scientist might argue that this overlap is excessive but some of the most elegant and sophisticated fundamental basic research has been stimulated by clinical problems. Arthur Broadus and Andrew Stewart, of the Endocrine Section at Yale, and their colleagues carefully studied patients hospitalized with hypercalcemia associated with malignancy and ultimately extracted the factor responsible and cloned the gene which produces it. David Tilson noticed a difference in the ratio of males to females in a series of patients with abdominal aortic aneurysms versus those with aortic occlusive disease. This simple observation and his dogged persistence has produced fundamental biochemical information about the genetics and metabolism of collagen. These basic studies were directly inspired by clinical problems and carried out by clinician scientists. And there are many other examples within our community alone. One of the problems that has fascinated me is the way that regulatory mechanisms have evolved in biological systems. Consider the following paradox: calcium

BARBARA K. KINDER, M.D., Associate Professor of Surgery, Department of Surgery, Yale University School of Medicine.

* Presidential Address to the Connecticut Society of American Board of Surgeons.

ion is both toxic to and required for living cells. The calcium concentration in the primordial ocean is believed to have been much lower than it became by the time that cellular organisms evolved. Direct contact with higher calcium levels would have resulted, for example, in protein aggregation and precipitation and cell death. So cells developed ways to isolate the calcium so abundant in the environment.

RESEARCH



TEACHING

PATIENT CARE

Figure 1

The result is that the extracellular calcium level is ten thousand-fold higher than the intracellular level. This is ingenious enough but evolution has taken advantage of this gradient across the cell membrane to use calcium as a messenger. Many stimuli, we now know, result in a transient increase in intracellular calcium which stimulates a host of chemical reactions until the calcium level is brought back to normal. These reactions ultimately result in what we see as the physiologic result of the initial stimulus whether it be mechanical, chemical, electrical, or hormonal. Because of my academic practice in endocrine surgery, I see a lot of patients with hyperparathyroidism. I was intrigued by the fact that although calcium in most systems acts to stimulate a cell to, say, release a hormone, in the parathyroid the opposite occurs. That is, a rise in calcium within the physiologic range inhibits parathyroid hormone secretion. I was fortunate several years ago to begin collaborative work with Fred Gorelick in the GI Section and Jim Jamieson in Cell Biology, who have helped me begin to investigate these intriguing questions. We have purified an enzyme from parathyroid tissue which, when activated by calcium, may participate in the regulation of parathyroid hormone secretion either by facilitating intracellular degradation of hormone or by interfering with one or more of the complex mechanisms which result in exocytosis.¹

I hope I've made academic surgical inquiry sound like fun—it is, but there are some very real problems. As I

mentioned at the beginning of this talk, the mid-faculty level in an academic career has been shown to be a watershed time. It is a time when academic faculty may decide to make a career change and perhaps leave the university setting. Of the factors that have been identified as critical in determining the satisfaction of academic surgeons with their career choice, I would mention two. In the first place, as you are all aware, there has been a significant change in the pattern of revenue sources for medical schools. Whereas in 1965, 55% of medical school revenue derived from federal sources, by 1984 the percentage had dropped to 25%.³ Medical schools have made up the difference in several ways: by obtaining funding from industry and increasingly from clinical practice income. For academic surgeons this dependence on practice income has had particular significance. Medical school deans and department chairman have understandably encouraged academic surgeons to increase their clinical activities and thus their contributions to the school and departmental coffers, and faculty surgeons, being surgeons first and foremost, have happily complied. The end result is that, in a recent study by the National Academy of Science committee on national needs for biomedical and behavioral research, surgeons were shown to work on average 20% more hours per week than their colleagues in internal medicine and basic science. No big surprise there, but the disturbing fact was that the percentage of time spent doing research was the lowest for surgeons: 20% compared with 40% for internists and 60% for basic scientists. Small wonder that in 1984 only 3% of NIH grants were awarded to surgeons—a fourfold decrease since 1974.⁴ A Conjoint Council on Surgical Research, convened as these sorts of data were coming to light, concluded that the reason for our poor showing in NIH grants was that too few applications were being submitted and there was a lack of high quality submissions. Today's academic surgeon too often has neither the time (too busy operating) or the training (we say it takes five years to train a general surgeon—how long does it take to train a scientist?) to be competitive for grant support. I am not implying that it is necessary to have a Ph.D. to lead a successful academic life in surgery, but solid training in research, protected time to continue investigative efforts, and the ability periodically to retool one's scientific skills by intensive interaction with basic science colleagues have been shown to increase the likelihood of success for a surgeon scientist. The difficulty is in achieving a balance between clinical surgery, which is our basic identity, and scientific inquiry, toward which many of us are compellingly drawn by the unsolved problems of our patients. Probably Dr. Francis Moore, in assessing his experience over a lifetime in academic surgery, said it most succinctly:

There exists a conflict of interest in academic surgery which is entirely unresolved...the conflict between the operating room and the laboratory...between the clinical pressures of care of the sick and the pursuit of science. There have been few academic surgeons who have not suffered, to some extent, from this conflict. Although the university surgeon "builds the bridge" from laboratory science to the bedside, those who live on each side declare he does not belong on either side. He is not enough of a scientist to "belong" on that side, and his is always accused of not doing enough operations by the busy clinicians. And yet, ...all the basic advantages of science in surgery since Vesalius, Hunter, Lister, Halsted, and Cushing have been made by those willing to adopt this uncomfortable posture."⁵ For me, the effort to maintain this uncomfortable

posture continues to be outweighed by the satisfaction of participating in all three spheres of medicine. I believe that the knowledge, skill, and, most important, discipline, unique to each inform and enhance rather than detract from the conduct of patient care, teaching, and research.

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From the Executive Director's Office

CALL

SEMI-ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1989 Semi-Annual Meeting of the House of Delegates will be held at the Ramada Inn, 201 Washington Avenue, North Haven. The meeting will commence at 12:30 P.M. on Thursday, November 15, and will continue until all business has been concluded.

11:30 Registration and Luncheon
12:30 Call to Order

Roger S. Beck, M.D., President
Kenneth M. Robbins, M.D., Speaker
Marjorie G. Petro, M.D., Secretary

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides that:

Resolutions may be introduced by any Active, Life Member, Student Member or Postgraduate Physician Member of The Society, in compliance with the following provisions.

- All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.*
- Component county associations or the Student Member or Postgraduate Physician Member Associations whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports, and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc., be considered regular business if they are received later than fifteen days prior to the date of the meeting.*
- Reports, recommendations, resolutions, or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered regular business.*
- Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for considerations by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provisions of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.*

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Dietary Fiber and Health

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During the last 18 years, considerable research has been conducted on the role of dietary fiber in health and disease. Interest was stimulated by epidemiologic studies that associated a low intake of dietary fiber with the incidence of colon cancer, heart disease, diabetes, and other diseases and disorders. Dietary fiber is not a single substance. There are significant differences in the physiological effects of the various components of dietary fiber. A Recommended Dietary Allowance for dietary fiber has not been established. However, an adequate amount of dietary fiber can be obtained by choosing several servings daily from a variety of fiber-rich foods such as whole-grain breads and cereals, fruits, vegetables, legumes, and nuts.

EPIDEMIOLOGIC studies or clinical trials or both have examined the effects of fiber on carbohydrate metabolism (glycemic response), lipid metabolism, colon cancer, diverticular disease, constipation, weight reduction, and other conditions. Interpretation of these studies is complicated by (1) differences in methods used for measuring dietary intake and lack of a single agreed on method for measuring fiber content of foods in epidemiologic studies, and (2) differences in the type and level of fiber components and fiber-containing foods used in clinical trials.¹

Dietary Fiber

No precise and universally accepted definition of dietary fiber exists. The most popular definition is a physiological one based on the way dietary fiber behaves in the human gastrointestinal tract: *dietary fiber* is defined as "remnants of plant cells resistant to hydrolysis by the alimentary enzymes of man, the group of substances that remain in the ileum but are partly hydrolyzed by bacteria in the colon."²

From the Council on Scientific Affairs, American Medical Association, Chicago, Ill.

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This report is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all of the facts and circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and patterns of practice evolve. This report reflects the views of scientific literature as of April 1988.

Dietary fiber is not a single substance, but an extremely complex mixture of substances. Dietary fiber is composed of a variety of polysaccharides including cellulose, hemicellulose, pectic substances, gums, mucilages, algal polysaccharides (eg, agar and carrageen), and lignin, a nonpolysaccharide (Table 1). Dietary fibers can be classified according to water solubility. Depending on the method of extraction, the structural fibers (cellulose, lignin, and some hemicelluloses) are insoluble, and the natural gel-forming fibers (pectins, gums, mucilages, and remaining hemicelluloses) are soluble. Most foods of plant origin contain both soluble and insoluble dietary fiber. Food sources of fiber are complex, but they may be rich in one type of fiber or another. For example, oat bran is rich in gums and considered a good source of viscous fiber, while wheat bran contains more insoluble components. In general, vegetables and grain products are good sources of cellulose, and bran cereals and other whole-grain products are the most concentrated sources of hemicellulose. Legumes and oat products are the best sources of gums; apples and citrus fruits contain a large amount of pectin.

Physiological Effects

Evidence to date suggests that fiber is necessary to maintain normal functioning of the gastrointestinal tract.³ Sources of fiber vary considerably in their physical properties, chemical composition, and composition of the fiber containing matrix in foods. The physiochemical properties may be related to a wide range of physiological responses. Table 2 shows some of the physiochemical properties of fiber and the gastrointestinal events it may modify.⁴

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Table 1.—Components of Dietary Fiber Obtained From Plants*

Structural components of plant cell wall	Protein Lipids (eg, waxes) Inorganic constituents Lignin Cellulose Noncellulosic polysaccharides†	Dietary fiber
Nonstructural components either found naturally or used as food additives	Pectin Gums Mucilages Algal polysaccharides Modified cellulose	

*From reference 1.
†The noncellulosic polysaccharides of the plant cell wall include hemicellulose and pectic substances.

The physiological effects of dietary fiber occur throughout the length of the gastrointestinal tract and include subsequent systemic effects. High-fiber foods are “chewy,” and chewing stimulates the flow of saliva and the secretion of gastric juices. Water-soluble fibers, such as pectin, form gels and increase the viscosity and stickiness of the stomach contents. Viscous fibers delay gastric emptying. High-fiber meals fill the stomach and provide a feeling of satiety. Soluble fiber appears to slow the rate of digestion and absorption of foods, but the mechanism is not well understood. Dietary fiber increases fecal bulk and rate of passage through the large intestine. A number of factors are involved in fecal bulking. Most fibers contribute to increased stool volume and weight through an increase in undigested and nonfermentable material, bound water, and/or bacterial cell mass and gas produced during fermentation of soluble fibers.⁵ Fiber’s water-holding capacity prevents water from being absorbed through the colonic mucosa. This helps prevent dry, hard stools. Some fibers hold more water than others. For example, cellulose produces dry stools, but the combination of cellulose and pectin is a superior bulk-forming laxative.⁶ Water-holding capacity of some dietary fibers varies according to the physical characteristics of the food. For example, fine bran holds less water than coarse bran. In general, cereal grains are more

effective than fruits and vegetables in increasing the bulk of stools and preventing constipation.

Fiber also affects transit time, but the amount of fiber needed to regulate or “normalize” passage of waste through the intestines varies among individuals. Normal laxation is an individual matter and may range from one bowel movement a day to as many as three. Still others have a “normal” pattern of three bowel movements a week. Increased intake of dietary fiber has been shown to hasten transit time in persons with slow transit time and to prolong it in subjects with normally rapid transit.^{7,8} For example, a bulk-forming laxative has been used to treat diarrhea resulting from tube feeding.⁹

Fiber and Disease

The hypothesis that fiber has protective effects against many diseases has been under investigation for many years. Beginning in the 1960s, British scientists¹⁰⁻¹⁶ hypothesized that several diseases and disorders common in affluent western societies were related to a low intake of dietary fiber. These investigators reported that the diseases and disorders were rare in rural African blacks who had high-fiber diets and produced soft stools in large volume.¹⁷ In urban centers of Africa and in western cultures, where life-styles and diets are quite different from those of rural Africa, the incidence of these diseases is much higher.

In developing the “fiber hypothesis,” scientists described potential mechanisms of action. Thus, the hypothesis that a high-fiber diet could prevent certain diseases seemed plausible and stimulated a great deal of research in the following years. Although the fiber hypothesis has not been universally accepted, it led to research that improved our understanding of fiber and its effects. Obtaining proof of its effectiveness in disease prevention is extremely difficult because the diseases and disorders in question take many years to develop, and

Table 2.—Physicochemical, Physiological, and Clinical Aspects of Fiber*

Physicochemical Property	Type of Fiber	Physiological Effect	Clinical Implication
Viscosity	Gums, mucilages, pectins	↓ Gastric emptying,† ↑ mouth to cecum transit, ↓ rate of small intestinal absorption (eg, of glucose, bile acids)	Dumping syndrome Diabetes Hypercholesterolemia
Particle size and water-holding capacity	Eg, wheat bran, pentosan content, polysaccharide-lignin mixtures	↑ Gastric emptying, ↓ mouth to cecum transit, ↓ total gastrointestinal tract transit time, ↓ colonic intraluminal pressure, ↑ fecal bulk	Peptic ulcer Constipation Diverticular disease Dilute potential carcinogens
Adsorption and nonspecific effects	Lignin, pectin-mixed fibers	↑ Fecal steroids output, ↑ fecal fat and N losses (small)	Hypercholesterolemia Cholelithiasis
Cation exchange	Acidic polysaccharides (eg, pectins)	↑ Small intestinal losses of minerals (±), trace elements (±), heavy metals	Negative mineral balance, possibly compensated for by colonic salvage, antitoxic effect
Antioxidant	Lignin (reducing phenolic groups)	↓ Free radicals in digestive tract	Anticarcinogenesis?
Degradability (colonic bacteria)	Polysaccharides (free of lignin)	↑ Production of gas and SCFAs, ↓ cecal pH	Flatus, energy production

*Modified from reference 4.
† ↑ indicates increases; ↓, decreases; N, nitrogen; and SCFA, short-chain fatty acid.

their etiology is multifactorial. Moreover, many extrinsic factors play a part both in the diet and in the environment generally. Some of the diseases in which dietary fiber has been proposed to have a protective effect are discussed in the following sections.

Heart Disease

One of the risk factors for coronary artery disease is high blood cholesterol levels. In experimental studies, soluble fiber fractions (pectin, guar gum, barley, and oat bran) have been shown to reduce blood cholesterol levels, at least when given in large amounts.^{1,18} The fibers from fresh fruit, vegetables, legumes, oat bran, and barley appear to have the most potential for reducing cholesterol levels. Except for oats and barley, which are rich in β -glucans, cereal foods do not appear to have the same potential. Insoluble fibers such as wheat bran have essentially no effect on serum cholesterol levels.¹⁹ In most studies, the fibers used experimentally to lower cholesterol levels were extracted from foods and given as supplements in rather large quantities.

Mechanisms proposed for fiber's hypocholesterolemic effects include, among others, the following²⁰: (1) Soluble fibers bind bile acids and other lipids and may interfere with micelle formation in the proximal small intestine, resulting in alterations in the quantity of cholesterol or fatty acids absorbed or altering the size of lipoprotein particles formed by the intestinal mucosa. (2) Soluble fibers increase the fecal excretion of bile acids and may interfere with cholesterol and bile acid homeostasis sufficiently to affect hepatic secretion of lipoproteins. (3) Soluble fibers fermented by colonic bacteria form gases and short-chain fatty acids (predominantly acetate, propionate, and butyrate). Short-chain fatty acids are almost completely absorbed into the portal vein and could affect hepatic cholesterol synthesis.

Diets that contain various kinds and amounts of fiber are likely to differ in other ways. For example, diets high in fiber often contain less fat and cholesterol and provide less energy than those low in fiber. The types of fat also may differ significantly. Thus, fiber is only one of several dietary components that may affect blood cholesterol levels. No specific recommendations concerning dietary fiber intake and heart disease can be made at this time.^{1,18,21}

Cancer of the Colon

The prevalence of colon cancer varies widely among different populations of the world. In the United States, the incidence is high in both sexes. Also, like cancer of the breast and uterus, colon cancer is more common in obese persons.²² Some scientists believe that diet is an important contributing factor to colon cancer.

Evidence from population studies suggest that a high-fiber diet is protective while a high-fat diet may increase risk. Since high-fat diets usually include more meats and other sources of animal fats than low-fat diets, the type of fat in the diet may be important. The roles of dietary fiber and fat in colon cancer have not been clearly defined.

Energy intake is also of particular interest. Data collected over a 70-year period show that animals fed nutritionally adequate diets with low energy intake have lower cancer rates than those fed nutritionally adequate diets with high energy intake.

Several mechanisms have been proposed for fiber's protective effect against colon cancer.²¹ Fiber may act to reduce transit time in the bowel and thereby decrease the time for exposure to potential carcinogens; through its hydrophilic nature, fiber can dilute the concentration of carcinogens in the colon; it can affect the production of bile acids and other potential carcinogens in the stool; it can alter the nature of fecal bile acids by virtue of its influence on the composition and metabolic activity of fecal flora; and it can reduce colonic pH by increasing fermentation and short-chain fatty acid production.

Animal data have raised questions about fermentable fiber's effects on the large-bowel mucosa. Evidence is growing that highly fermentable fibers can enhance the development of experimental colon carcinogenesis.²³

The National Research Council Committee on Diet, Nutrition, and Cancer²⁴ found "no conclusive evidence to indicate that dietary fiber (such as that present in certain fruits, vegetables, grains, and cereals) exerts a protective effect against colorectal cancer in humans. Both epidemiologic and laboratory reports suggest that if there is such an effect, specific components of fiber, rather than total fiber, are more likely to be responsible." The report by the Federation of American Societies for Experimental Biology¹ and The Surgeon General's Report on Nutrition and Health²¹ reached similar conclusions.

Obesity

Heredity, overeating, and physical inactivity are important factors in the development of obesity. Some scientists believe that excessive energy intake may be inevitable when diets are low in fiber. High-fiber diets may reduce energy intake, even when more food is eaten. Studies suggest that when people are allowed to eat unlimited amounts of high-fiber food, but are not allowed to eat foods containing sugar and other refined carbohydrates, energy intake decrease significantly, and appetites are satisfied.²⁵ Although fiber has no magical effects in promoting weight loss, it can be an important part of a balanced diet with restricted energy intake. High-fiber diets also are beneficial because they help prevent constipation, a common result of reduced food intake. Limited data from clinical trials that suggest fiber supplements or high-fiber diets are useful for weight reduction are contradictory. Dietary fiber may have a limited role as an adjunct in the treatment of obesity, but controlled, long-term trials are needed before this can be established.¹

Diabetes

Both hereditary and nonhereditary factors are thought to be involved in non-insulin-dependent diabetes mellitus. Most persons with this disorder are over 40 years of

age and overweight. Weight reduction is important in treating this form of diabetes, and patients often benefit from a diet rich in complex carbohydrates, including fiber.^{26,27} Such diets may improve control of blood glucose and reduce the amount of medication needed. Simply adding fiber supplements to a poorly planned diet is of little value, however. A good balance of protein, carbohydrate, and fat is needed. Dietary fibers that have the greatest hypoglycemic effect are water soluble and viscous (ie, pectins, gums).

Gastrointestinal Disorders

A number of gastrointestinal problems may be relieved or prevented by a diet adequate in fiber; the size and texture of stools are directly related to fiber in the diet. Some scientists believe that the fiber from cereal grains is the most important for "normal" bowel function.

In addition to preventing and relieving constipation, fiber may relieve symptoms of diverticular disease. *Diverticulosis* is a condition in which little saclike swellings (diverticula) form in the wall of the colon and project into the abdominal cavity. In the United States, most people over 60 years of age have diverticulosis, although there usually are no symptoms.²⁸ In some cases, however, the diverticula become inflamed—a condition called "diverticulitis." Small, hard stools and strained bowel movements may lead to the formation of diverticula by increasing the pressures in the colon. If so, a diet adequate in fiber is an important preventive measure.

The incidence of hiatus hernia, abdominal hernias, hemorrhoids, and varicose veins is higher in persons with diverticular disease.²⁹ Hiatus hernia is rather common in the United States, particularly among overweight people. It has been suggested that upward pressure on the stomach from straining during bowel movements could result in such a hernia after a period of years. However, heredity and increased pressure in the abdominal cavity from coughing, vomiting, or physical exertion also could lead to hiatus hernia.

There is less agreement on the role of dietary fiber in prevention of gallstones, most of which are composed mainly of cholesterol. Animal and population studies suggest that diet can be an important factor in gallstone formation, which is more common in older and overweight individuals. Yet, other findings, such as the fact that in some tribes of American Indians, 75% of the women had gallstones by the age of 25 years, point toward heredity as a factor.³⁰

Report of the Federation of American Societies for Experimental Biology

Recently, an expert panel of the Life Sciences Research Office of the Federation of American Societies for Experimental Biology¹ completed an assessment of the role of dietary fiber in health. The panel evaluated various fiber sources in the prevention, amelioration, or treatment of specific diseases and disorders. The panel concluded that (1) many of the claimed benefits, including use in obesity,

diabetes, coronary heart disease, hyperlipidemia, hypertension, gallstones, peptic and duodenal ulcers, irritable bowel syndrome, inflammatory bowel disease, and colon cancer, have not been clearly demonstrated; and (2) results of studies to date are inconclusive or equivocal. The panel did conclude that dietary fiber, particularly wheat fibers and other insoluble fiber sources, is useful in the prevention and treatment of constipation. And finally, "the available evidence is not sufficient to support specific, quantitative recommendations on the role of dietary fiber for the prevention of specific diseases in the general, healthy population."

The report emphasized: "As a result of the diversity of effects of various components of dietary fiber, it is important that the dietary fiber consumed come from a wide variety of foods that provide a broad spectrum of these components. The members of the Expert Panel concurred that dietary fiber should be obtained from a variety of whole-grain products, fruits and vegetables, including legumes."

The Surgeon General's Report on Nutrition and Health

The primary focus of the report is the relationship between dietary factors and chronic disease risks, and the scientific basis for dietary recommendations to the general public. The report made the following recommendation for dietary fiber intake: "Complex carbohydrates and fiber: Increase consumption of whole grain foods and cereal products, vegetables (including dried beans and peas) and fruits."²¹

Recommended Intakes

Information on levels of dietary fiber intakes in the U.S. population is very limited, and available only for adults.¹ Data have been derived using a variety of measurement methods (diet records, food disappearance, experimental diets, etc) and are based on a variety of methods of food analysis. There is no single, universally acceptable method for determining total dietary fiber. Analytic procedures may yield dietary fiber values for a single food that differ by 100%.¹ Currently, US food composition tables give values for "crude fiber." The procedures for determining crude fiber destroy all the soluble fiber fraction and variable amounts of insoluble fiber. Thus, total dietary fiber content, the sum of soluble and insoluble fibers, is greatly underestimated. Estimates for fiber intake for US adults range from 2.5 to 4.8 g/d (1.5 to 2.9 g/4200 kJ), to 11.1 to 23.3 g/d (5.8 to 11.8 g/4200 kJ) depending on the analytic procedure used.¹

The ideal dietary fiber intake has not been defined; a Recommended Dietary Allowance³¹ for dietary fiber has not been established. However, there is general agreement that dietary fiber is part of a healthful diet. The advice concerning dietary fiber, "eat foods with adequate starch and fiber," given in *Dietary Guidelines for Americans*³² seems reasonable. An adequate amount of dietary fiber can be obtained by choosing several servings daily from a variety of fiber-rich foods such as whole-grain

breads and cereals, fruits, vegetables, legumes, and nuts (Table 3).

Adverse Effects of Fiber

When fiber intake is increased significantly, gas, intestinal distension, and diarrhea may occur. These side effects are caused by bacterial fermentation of fiber with release of volatile fatty acids, hydrogen, carbon dioxide, and methane. Dietary fiber intake should be increased gradually along with adequate fluid intake so the gastrointestinal tract can adjust to the change. The gastrointestinal disturbances associated with initial fiber ingestion should subside within 24 to 48 hours.

Very large intakes of fiber have been reported to cause colon obstruction. This is far more likely to occur with improper use of fiber supplements and laxatives than with fiber-rich foods. When fiber intakes are increased, it is important to increase the intake of liquids.

Fiber may interfere with the absorption of some minerals. However, this does not seem to pose a problem for people with adequate nutrient intakes. Moderate levels of fiber intake are unlikely to cause nutrient deficiencies.^{1,29} Consumption of fiber from a wide variety of food sources is recommended to decrease possible adverse effects from increased consumption of fiber.¹

Supplements

Purified fibers or fiber supplements are not generally recommended. The full range of possible health benefits from dietary fibers depends on consumption of a variety of plant foods; for example, a bran supplement cannot provide the benefits of pectins or gums and vice versa. Whole-grain cereal-based foods increase the bulk of stools and relieve symptoms of a number of common gastrointestinal disorders, but most (oats and barley are exceptions) do not affect blood cholesterol levels. Fruits and vegetables appear to be most effective in lowering blood cholesterol levels, slowing stomach emptying time, and decreasing the rate of food absorption. Oat bran and barley are cereal foods rich in water-soluble fiber and thus have effects more similar to those of fruits and vegetables than to those of other cereals. However, some individuals cannot or will not increase their intake of high-fiber foods, and for these a particular supplement with increased intake of liquids to prevent complications such as obstruction in the colon might be recommended.

Summary

Dietary fiber is not a single substance but an extremely complex mixture of substances. Evidence to date suggests that dietary fiber is necessary to maintain normal functioning of the gastrointestinal tract and that dietary fiber is useful in the prevention and treatment of constipation.

There is general agreement that dietary fiber is part of a healthful diet. Advice concerning dietary fiber—"eat food with adequate fiber"—given in the *Dietary Guidelines for Americans* by the US Department of Agriculture and US Department of Health and Human Services seems reasonable. An adequate amount of dietary fiber

Table 3. —Dietary Fiber Content of Selected Foods*

Food	Serving	kJ (Calories)	Dietary Fiber, g
Fruits			
Apple (with skin)	1 medium	340 (81)	3.5
Banana	1 medium	440 (105)	2.4
Cantaloupe	¼ melon	130 (30)	1.0
Cherries, sweet	10	200 (49)	1.2
Peach (with skin)	1	150 (37)	1.9
Pear (with skin)	½ large	260 (61)	3.1
Prunes	3	250 (60)	3.0
Raisins	¼ cup	440 (106)	3.1
Raspberries	½ cup	150 (35)	3.1
Strawberries	1 cup	190 (45)	3.0
Orange	1 medium	260 (62)	2.6
Vegetables, cooked			
Asparagus, cut	½ cup	60 (15)	1.0
Beans, string, green	½ cup	70 (16)	1.6
Broccoli	½ cup	80 (20)	2.2
Brussels sprouts	½ cup	120 (28)	2.3
Parsnips	½ cup	210 (51)	2.7
Potato (with skin)	1 medium	440 (106)	2.5
Spinach	½ cup	90 (21)	2.1
Sweet potato	½ medium	340 (80)	1.7
Turnip	½ cup	70 (17)	1.6
Zucchini	½ cup	50 (11)	1.8
Vegetables, raw			
Celery, diced	½ cup	40 (10)	1.1
Cucumber	½ cup	30 (8)	0.4
Lettuce, sliced	1 cup	40 (10)	0.9
Mushrooms, sliced	½ cup	40 (10)	1.5
Tomato	1 medium	80 (20)	1.5
Spinach	1 cup	30 (8)	1.2
Legumes			
Baked beans	½ cup	650 (155)	8.8
Dried peas, cooked	½ cup	480 (115)	4.7
Kidney beans, cooked	½ cup	460 (110)	7.3
Lima beans, cooked	½ cup	270 (64)	4.5
Lentils, cooked	½ cup	410 (97)	3.7
Navy beans, cooked	½ cup	470 (112)	6.0
Breads, pastas, and flours			
Bagels	1 bagel	610 (145)	0.6
Bran muffins	1 muffin	440 (104)	2.5
French bread	1 slice	430 (102)	0.7
Oatmeal bread	1 slice	260 (63)	0.5
Pumpnickel bread	1 slice	300 (66)	1.0
Whole wheat bread	1 slice	260 (61)	1.4
Rice, brown, cooked	½ cup	440 (97)	1.0
Spaghetti, cooked	½ cup	650 (155)	1.1
Nuts and seeds			
Almonds	10 nuts	330 (79)	1.1
Peanuts	10 nuts	440 (105)	1.4
Pilberts	10 nuts	230 (54)	0.8
Popcorn, popped	1 cup	230 (54)	1.0
Breakfast cereals			
All-Bran	½ cup	300 (71)	8.5
Bran Buds	½ cup	310 (73)	7.9
Bran Chex	¾ cup	380 (91)	4.6
Corn Bran	¾ cup	410 (98)	5.4
40% Bran-type	¾ cup	400 (93)	4.0
Raisin Bran-type	¾ cup	480 (115)	4.0
Shredded wheat	¾ cup	438 (102)	2.6
Oatmeal, regular, quick, and instant, cooked	¾ cup	450 (108)	1.6
Comflakes	1 ¼ cup	460 (110)	0.3

*The data are from *Fiber Facts*. Chicago, Ill: The American Dietetic Association; 1986.

can be obtained by choosing several servings daily from a variety of fiber-rich foods such as whole-grain breads and cereals, fruits and vegetables, legumes, and nuts.

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AROUND THE STATE

Programs and Courses

The Yale University School of Medicine, Departments of Psychiatry and Neurology and the Office of Postgraduate and Continuing Medical Education announce their new semi-annual comprehensive review of psychiatry and neurology under the direction of Harvey L. Ruben, M.D., M.P.H.

Courses will be held on 14-22 October 1989 and 27 January to 4 February 1990, and will meet the criteria for 61 hours (14 neurology, 35 psychiatry, 12 clinical interview) in category 1 of the Physician's Recognition Award of the American Medical Association.

For further information call (203) 785-4578.

The Yale University School of Medicine, Division of Gynecologic Oncology, Yale Comprehensive Cancer Center and the University of Connecticut School of Medicine announce their Seventh Annual Ella T. Grasso Memorial Conference, Wednesday 15 November 1989 at the Park Plaza, 155 Temple Street, New Haven.

For further information and registration contact the Postgraduate and Continuing Medical Education, Yale University School of Medicine, 333 Cedar St., New Haven, (203) 785-4578.

The Pediatric Pulmonary Division, Department of Pediatrics, The University of Connecticut School of Medicine will present the Inaugural Annual Pediatric Pulmonary Conference: "The Management of Chronic Asthma in Children" Thursday, 2 November 1989 in the Keller Auditorium, University of Connecticut Health Center, Farmington, from 1:30 P.M. to 8:30 P.M.

Michele M. Cloutier, M.D. and Jeanne F. Boulay, R.N., C.P.N.P. are the program directors. For more information call (203) 679-3340.

The University of Connecticut School of Medicine, Department of Surgery, Section of Colon and Rectal Surgery will present a course on Colon and Rectal Disease: Primary Care and Surgery on Friday, 17 November 1989 in the Keller Auditorium at the University of Connecticut Health Center, Farmington.

David A. Cherry, M.D., Clinical Assistant Professor of Surgery is the program director. Those interested should call Cecile J. Volpe at (203) 679-3340.

The Department of Obstetrics and Gynecology, Yale University School of Medicine, will sponsor a course in Diagnostic Ultrasound in Obstetrics on Monday and Thursday 4 - 7 December 1989 in the Max Taffel Room, Memorial Unit, Yale-New Haven Hospital.

This course has been approved for 27 cognates by the American College of Obstetricians and Gynecologists, and for 27 hours in Category 1 Continuing Medical Education toward the Physician Recognition Award of the American Medical Association and the American College of Radiologists.

For more information call 785-4578.

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Urinary Incontinence in Adults

NATIONAL INSTITUTES OF HEALTH

Introduction

URINARY incontinence, the involuntary loss of urine so severe as to have social and/or hygienic consequences, is a major clinical problem and a significant cause of disability and dependency. Urinary incontinence affects all age groups and is particularly common in the elderly. At least 10 million adult Americans suffer from urinary incontinence, including approximately 15% to 30% of community-dwelling older people and at least half of all nursing home residents. The monetary costs of managing urinary incontinence are conservatively estimated at \$10.3 billion annually and the psychosocial burden of urinary incontinence is great.

Urinary incontinence is a symptom rather than a disease. It appears in a limited number of clinical patterns, each having several possible causes. In some cases, the disorder is transient, secondary to an easily reversed cause such as a medication or an acute illness like urinary tract infection. Many cases are chronic, however, lasting indefinitely unless properly diagnosed and treated.

There is a persistent myth that urinary incontinence is a normal consequence of aging. While normal aging is not a cause of urinary incontinence, age-related changes in lower urinary tract function predispose the older person to urinary incontinence in the face of additional anatomic or physiological insults to the lower urinary tract or by systemic disturbances such as illnesses common in older people.

Even frail nursing home residents or persons being cared for by family care givers often have urinary incontinence that can be significantly improved or cured. Persons with urinary incontinence should be alerted to the importance of reporting their symptoms to a health care professional and of asserting their right to proper assessment, diagnosis, and treatment. The first steps to

treatment are acknowledgment of the problem and appropriate assessment and diagnosis.

Knowledge of the occurrence, causes, consequences, and treatment of the specific forms of urinary incontinence has increased. While new diagnostic tests have been developed, well-defined guidelines are needed for their application. Similarly, despite numerous new potential therapies, opinions differ widely concerning the best approach to many specific forms of the disorder. The most common treatments include pelvic muscle exercises and other behavioral treatments, local and systemic drug therapies, and a variety of surgical approaches.

The number of patients with urinary incontinence who are not successfully treated remains surprisingly high. This is due to several factors, including underreporting by patients; underrecognition as a significant clinical problem by health care providers; lack of education of health providers regarding new research findings; inadequate staffing in the long-term—care setting; and the persistent major gaps in our understanding of the natural history, pathophysiology, and most effective treatments of the common forms of urinary incontinence. The amount of basic research as well as research focusing on prevention is meager.

To resolve issues regarding the incidence, causes, treatment, and consequences of urinary incontinence in adults, the National Institute on Aging and the Office of Medical Applications of Research of the National Institutes of Health, in conjunction with the National Institute of Diabetes and Digestive and Kidney Diseases, the National Center for Nursing Research, the National Institute of Neurological Disorders and Stroke, and the Veterans Administration, convened a Consensus Development Conference on Urinary Incontinence in Adults on October 3 through 5, 1988. After a day and a half of presentations by experts in the relevant fields involved with urinary incontinence, a consensus panel consisting of representatives from geriatrics, urology, gynecology, psychology, nursing, epidemiology, basic sciences, and the public considered the evidence and developed answers to the following central questions:

From the Office of Medical Applications of Research, National Institutes of Health, Bethesda, Md.

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1. What are the prevalence and the clinical, psychological, and social impact of urinary incontinence among persons living at home and in institutions?

2. What are the pathophysiological and functional factors leading to urinary incontinence?

3. What diagnostic information should be obtained in assessment of the incontinent patient? What criteria should be employed to determine which tests are indicated for a particular patient?

4. What are the efficacies and limitations of behavioral, pharmacologic, surgical, and other treatments for urinary incontinence? What sequences and/or combination of these interventions are appropriate? What management techniques are appropriate when treatment is not effective or indicated?

5. What strategies are effective in improving public and professional knowledge about urinary incontinence?

6. What are the needs for future research related to urinary incontinence?

1. What Are the Prevalence and the Clinical, Psychological, and Social Impact of Urinary Incontinence Among Persons Living at Home and in Institution? —

Estimates of the occurrence of urinary incontinence depend on the nature of the study population and the definition of the disorder. Prevalence rates range from 8% to 51%; an estimate of 15% to 30% for community-dwelling older persons seems reasonable, and of these 20% to 25% may be classified as severe cases. Prevalence rates are twice as high in women as in men and are higher in older than in younger adults. Though these community rates are alarmingly high, rates in nursing homes are even higher. Half or more of the 1.5 million Americans in nursing homes suffer from urinary incontinence.

Little is known about the natural history of urinary incontinence, including age at onset, incidence rates, progression, and spontaneous remission. Limited data exist on associated morbidity and functional impairment. To date, most studies have been conducted in whites, and data are needed on the occurrence in non-white ethnic groups.

Though urinary incontinence is a symptom of many conditions, defining risk factors would be extremely useful for identifying high-risk persons and remediable environmental causes. While age, gender, and parity are established risk factors, many other factors have been suggested but not rigorously proved. These include urinary tract infection, menopause, genitourinary surgery, lack of postpartum exercise, chronic illnesses, and various medications. Identification of risk factors is essential for a concerted effort at prevention.

Clinical, Psychological, and Social Impact

In the Community.—Because only about half of the people with incontinence in the community have consulted a physician about the problem, the true extent and clinical impact of urinary incontinence are not known. Rashes, pressure sores, skin and urinary tract infections,

and restriction of activity are some of the problems that could be prevented or treated if the underlying incontinence were brought to medical attention. Many people with incontinence turn prematurely to the use of absorbent materials without having their difficulty properly diagnosed and treated.

The psychosocial impact of incontinence in the community falls on individuals and their care providers. Studies of women show that the condition is associated with depressive symptoms and leads to embarrassment about appearance and odor, although such reactions may be related more to illness than to incontinence. Excursions outside the home, social interactions with friends and family, and sexual activity may be restricted or avoided entirely in the presence of incontinence. Spouses and other intimates also may share the burden of this condition. A highly conservative estimate of the direct costs of caring for persons with incontinence of all ages in the community is \$7 billion annually in the United States.

In Nursing Homes.—Many physicians fail to recognize the clinical impact of urinary incontinence in nursing homes, and very few nursing home residents with incontinence have had any type of diagnostic evaluation. In this setting, fecal incontinence, physical and mental impairment, pressure sores, and urinary tract infections are commonly associated with urinary incontinence, but cause-and-effect relationships are not clear. Many nursing home residents who are incontinent are managed with indwelling catheters, which carry an increased risk of significant urinary tract infection, and the use of such devices varies widely. The odor of urine that permeates many nursing homes can be repellent to residents, staff, and potential visitors. Managing those with incontinence presents a major problem to insufficient and often untrained staff. The annual direct cost of caring for incontinence among nursing home residents is approximately \$3.3 billion.

2. What Are the Pathophysiological and Functional Factors Leading to Urinary Incontinence? —Continence requires a compliant bladder and active sphincteric mechanisms, such that maximum urethral pressure always exceeds intravesical pressure. Normal voiding requires sustained and coordinated relaxation of the sphincters and contraction of the urinary bladder.

These functions are regulated by the central nervous system through autonomic and somatic nerves. The system requires the integration of visceral and somatic muscle function and involves control by voluntary mechanisms originating in the cerebral cortex. These voluntary mechanisms are learned and culturally prescribed (ie, toilet training).

Incontinence can be produced by any pathological, anatomic, or physiological factor that causes intravesical pressure to exceed maximum urethral pressure. Intravesical pressure can be raised by involuntary detrusor con-

tractions (unstable bladder or detrusor hyperreflexia), by acute or chronic bladder overdistension (urinary retention with overflow), or by an increase in intra-abdominal pressure. Similarly, a decrease in urethral pressure may occur as a result of uninhibited sphincter relaxation (unstable urethra), loss of pelvic floor support (genuine stress incontinence), and urethral wall defects from trauma, surgery, or neurological disease.

The most commonly encountered clinical forms of urinary incontinence in adults are stress incontinence, urge incontinence, overflow incontinence, and a mixed form. In stress incontinence, dysfunction of the bladder outlet leads to leakage of urine as intra-abdominal pressure is raised above urethral resistance while coughing, bending, or lifting heavy objects. The volume of urine leakage is generally modest at each occurrence and, in uncomplicated cases, postvoid residual volume is low. Stress incontinence has many causes, including direct anatomic damage to the urethral sphincter (sphincteric incontinence), which may lead to severe, continuous leakage, and weakening of bladder neck supports, as is often associated with parity.

Urge incontinence occurs when patients sense the urge to void (urgency), but are unable to inhibit leakage long enough to reach the toilet. In most, but not all, cases, uninhibited bladder contractions contribute to the incontinence. Urine loss is moderate in volume and occurs at intervals of several hours and postvoid residual volume is low at intervals of several hours. Among the causes of urge incontinence are central nervous system lesions such as occur in stroke or demyelinating disease, which impair inhibition of bladder contraction, and local irritating factors such as urinary infection or bladder tumors. In many cases of urge incontinence, no specific etiology can be identified despite detailed clinical and laboratory evaluation.

An important variant of urge incontinence is reflex incontinence, in which urine is lost owing to uninhibited bladder contractions in the absence of the symptoms of urgency. In addition, many persons suffer from very frequent symptoms of urgency and are able to remain continent only by conducting their activities in the proximity of restrooms.

Overflow incontinence occurs when the bladder cannot empty normally and becomes overdistended, leading to frequent, sometimes nearly constant, urine loss. Causes include neurological abnormalities that impair detrusor contractile capacity, including spinal cord lesions, and any factor that obstructs outflow, including medications, tumors, benign strictures, and prostatic hypertrophy.

Many cases of urinary incontinence fall into the mixed category, displaying some aspects of more than one of the major subtypes, both clinically and on extensive laboratory evaluation.

The term *functional incontinence* is applied to those cases in which the function of the lower urinary tract is

intact, but other factors such as immobility or severe cognitive impairment result in urinary incontinence.

It should be clear that urinary incontinence can be caused by multiple and often interacting conditions. Of particular importance are the transient or reversible factors, such as infection, delirium, and drugs. These causes, which may be common in the elderly patient, should be carefully considered in the pathophysiology of urinary incontinence.

There are age-related changes in the lower urinary tract that increase its vulnerability to both chronic and transient factors. Increases in uninhibited contractions, nocturnal fluid excretion, and prostate size, accompanied by decreases in bladder capacity and flow rate, all lead to greater susceptibility to urinary incontinence in the face of stresses associated with disease, functional impairment, or environmental factors. In older persons, cognitive decline, musculoskeletal impairments, and restricted access to toilets may all convert the marginally continent system to incontinence.

3. What Diagnostic Information Should Be Obtained in Assessment of the Incontinent Patient? What Criteria Should Be Employed to Determine Which Tests Are Indicated for a Particular Patient?—Evaluation and therapy must be tailored to the individual, taking into account clinical, cognitive, functional, and residential status in addition to the potential for correcting the problem. Just as a child is not simply a young adult, octogenarians differ from persons in their 40s. Patients with stress urinary incontinence are quite dissimilar from those with uninhibited contractions and unstable bladders. Proper diagnosis and active case finding are imperative.

Core Evaluation

History.—The evaluation of all patients with incontinence requires a thorough history, including medical, urologic, gynecologic, and neurological assessment, with particular attention to those factors that influence bladder function. The duration, frequency, volume, and type of incontinence should be described and validated by a voiding diary. Other important information includes associated illnesses, previous operations, and current medications.

Physical Examination.—Physical examination is required, with emphasis on mental status; mobility and dexterity; and neurological, abdominal, rectal, and pelvic findings. A provoked full-bladder stress test is recommended. Since prostate enlargement is often asymmetric, the size of the prostate as estimated on rectal examination may be misleading when evaluating the possible contribution of prostatic hypertrophy to urinary obstruction.

In addition to the history and physical examination, core measurements to be obtained in all patients are urinalysis values, serum creatinine or blood urea nitrogen levels, and postvoid residual urine volume. Other tests such as urine culture, blood glucose, and urinary

cytology may be useful.

Based on the findings from the core evaluation, a decision for treatment or more definitive evaluation is made, taking into consideration the type and degree of incontinence.

Specialized Studies

The tests currently available for specialized study include the following:

- Cystometrogram—to be used as the basic study in cases requiring more than core evaluation—should be accompanied by measurement or estimation of abdominal pressure.
- Electrophysiological sphincter testing.
- Ultrasound evaluation of the bladder or kidneys may detect residual urine or hydronephrosis.
- Cystourethroscopy with or without cytological analysis is indicated in patients with hematuria or the recent onset of urgency or urge incontinence who are at increased risk for carcinoma.
- Uroflometry has wide application in the evaluation of obstructive disease in men, but a limited role in the evaluation of women.
- Video urodynamic evaluation requires special expertise. Its role is limited to the more elusive incontinence problems.
- Urethral pressure profilometry is a controversial test. Its predictive value has been questioned, and it requires further validation before it can be recommended for widespread use.

These numerous noninvasive and invasive tests must be used selectively. Examples of patients rarely requiring further diagnostic testing after the core examination include the young woman with classic stress incontinence or the 80-year-old women with a recent stroke and the new onset of urge incontinence. Patients with stress incontinence and a significant urge component or those in whom previous operations have failed may require combined cystography and fluoroscopy with a complete urodynamic evaluation. Some patients with urge or mixed incontinence, or those who are not helped by empirical therapy or operation, also will require more complete urodynamic testing. Some patients may not be candidates for sophisticated studies owing to inability to cooperate or a poor prognosis for correction. Armed with this information, the investigating physician should be able to reach an accurate diagnosis leading to appropriate therapy.

4. What Are the Efficacies and Limitations of Behavioral, Pharmacologic, Surgical, and Other Treatments for Urinary Incontinence? What Sequences and/or Combination of These Interventions Are Appropriate? What Management Techniques Are Appropriate When Treatment Is Not Effective or Indicated?—General principles of treatment are as follows:

- All persons with incontinence should be considered for evaluation and treatment.

- Treatment decisions should be based on a diagnosis made after a reasonable evaluation of anatomy and function of urine storage and emptying.

- Treatment for incontinence is given to a specific individual, whose personality, environment, expectations, and clinical status are important determinants of treatment modalities to be used and the order of their application.

- The patient requires sufficient information and explanation to be able to make a choice among therapeutic options.

- Environmental constraints in the community or in an institution that may impede treatment are common and strategies to circumvent impediments are a part of the therapy.

- In particular, availability of adequate numbers of properly constructed public toilets is an important adjunct to incontinence management.

Pharmacologic Treatment

Most drugs currently used in managing the varied causes of urinary incontinence have not been studied in well-designed clinical trials. Nevertheless, it has been suggested that many agents are beneficial, especially for patients with urge incontinence due to uninhibited detrusor contractions. For these patients, drugs that increase bladder capacity can be helpful. One attendant risk is the precipitation of retention. Accordingly, outlet obstruction or a weak detrusor should be looked for as possible contraindications to these agents.

Bladder Relaxants.— These agents are generally used for urge incontinence:

- *Anticholinergics.*—Anticholinergic agents inhibit detrusor contraction and may produce increased bladder capacity and delay and reduction in amplitude of involuntary contractions. Propantheline is frequently effective, although high doses may produce unacceptable side effects such as dry mouth, dry eyes, constipation, confusion, or precipitation of glaucoma.

- *Direct Smooth-Muscle Relaxants.*—These antispasmodics work directly on bladder muscle, but they have a mild anticholinergic effect as well. A randomized, double-blind, placebo-controlled study has shown benefit with oxybutynin in patients with detrusor instability, some but not all of whom were incontinent. Favorable reports also exist about flavoxate and dicyclomine, the other two agents in this class.

- *Calcium Channel Blockers.*—These agents, used clinically for cardiovascular indications, have a depressant effect on the bladder as well, but they have not been studied rigorously for the treatment of urge incontinence in comparison with other agents. In the patient being considered for treatment for heart disease, the bladder effects of calcium antagonists must be kept in mind for both their potential benefit as well as risk of retention.



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Consult the package literature for prescribing information.

Indication: Lower respiratory infections, including pneumonia, caused by *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Streptococcus pyogenes* (group A β -hemolytic streptococci).

Contraindication: Known allergy to cephalosporins.

Warnings: CECLOR SHOULD BE ADMINISTERED CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. PENICILLINS AND CEPHALOSPORINS SHOW PARTIAL CROSS-ALLERGENICITY. POSSIBLE REACTIONS INCLUDE ANAPHYLAXIS.

Administer cautiously to allergic patients.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It must be considered in differential diagnosis of antibiotic-associated diarrhea. Colon flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis.

Precautions:

- Discontinue Ceclor in the event of allergic reactions to it.
- Prolonged use may result in overgrowth of nonsusceptible organisms.
- Positive direct Coombs' tests have been reported during treatment with cephalosporins.
- Ceclor should be administered with caution in the presence of markedly impaired renal function. Although dosage adjustments in

moderate to severe renal impairment are usually not required, careful clinical observation and laboratory studies should be made.

- Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

- Safety and effectiveness have not been determined in pregnancy, lactation, and infants less than one month old. Ceclor penetrates mother's milk. Exercise caution in prescribing for these patients.

Adverse Reactions: (percentage of patients)

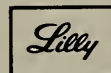
Therapy-related adverse reactions are uncommon. Those reported include:

- Gastrointestinal (mostly diarrhea): 2.5%.
- Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment.
- Hypersensitivity reactions (including morbilliform eruptions, pruritus, urticaria, and serum-sickness-like reactions that have included erythema multiforme [rarely, Stevens-Johnson syndrome] and toxic epidermal necrolysis or the above skin manifestations accompanied by arthritis/arthralgia, and frequently, fever): 1.5%; usually subside within a few days after cessation of therapy. Serum-sickness-like reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

- Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.
 - As with some penicillins and some other cephalosporins, transient hepatitis and cholestatic jaundice have been reported rarely.
 - Rarely, reversible hyperactivity, nervousness, insomnia, confusion, hypertonia, dizziness, and somnolence have been reported.
 - Other: eosinophilia, 2%; genital pruritus or vaginitis, less than 1% and, rarely, thrombocytopenia.
- Abnormalities in laboratory results of uncertain etiology**
- Slight elevations in hepatic enzymes.
 - Transient fluctuations in leukocyte count (especially in infants and children).
 - Abnormal urinalysis; elevations in BUN or serum creatinine.
 - Positive direct Coombs' test.
 - False-positive tests for urinary glucose with Benedict's or Fehling's solution and Clinistest[®] tablets but not with Tes-Tape[®] (glucose enzymatic test strip, Lilly).

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• **Imipramine.**—This tricyclic antidepressant has anticholinergic and direct relaxant effects on the detrusor and an alpha-adrenergic enhancing (contracting) effect on the bladder outlet, all of which enhance continence. Although imipramine is commonly used, potential side effects of postural hypotension and sedation as well as peripheral anticholinergic effects make caution imperative when considering this agent in older persons.

Bladder Outlet Simulants.—Alpha-adrenergic agonists, used in treatment of stress incontinence, produce smooth-muscle contraction at the bladder outlet and may improve continence. Pseudoephedrine and ephedrine both are active, but phenylpropanolamine has been used most often and objective benefit by urodynamic study has been shown.

Estrogens.—Because urinary incontinence increases in women with increasing age, and because menopause results in estrogen deficiency, estrogen replacement has been thought to be helpful for urinary incontinence. Several studies have shown no improvement in stress incontinence, but women with postmenopausal urge incontinence, urgency, and frequency have shown improvement. Long-term use should be considered in view of other risks and benefits.

Surgery

Surgery is particularly effective in treatment of pure stress incontinence associated with urethrocele. A variety of surgical techniques for the transvaginal or transabdominal suspension of the bladder neck yield a success rate between 80% and 95% in appropriately selected patients with stress incontinence at 1-year follow-up. Long-term results require study. When incontinence in men is secondary to outflow obstruction and chronic retention is secondary to prostatic enlargement, it is best treated with prostatectomy.

In addition, there are several specialized and more extensive surgical procedures. When incontinence is due to intrinsic sphincter dysfunction, which may occur after the surgical trauma of radical prostatectomy or sphincter denervation, the compressive action of the sphincter is lost. An implantable prosthetic sphincter can restore this compression. Continence is restored in 70% to 90% of patients in various series. A complication rate greater than 20% includes erosion of the urethra, infection, and mechanical failure. Reoperations are frequently required.

Urethral sling procedures pass a ribbon of fascia or artificial material beneath the urethra. The sling, fixed to the anterior body wall, serves to elevate and compress the urethra, restoring continence in 80% of patients. Bladder augmentation with isolated bowel segments will increase bladder capacity and vent excessive bladder pressure. This procedure is limited to certain specific bladder problems such as the contracted bladder of neurological disease or tuberculosis. Bladder replacement with continent diversion can also be offered to the cystectomy patient.

There are no simple procedures to control bladder instability or sensory urgency. When incontinence is due to a mixture of stress and urge, pharmacologic or behavioral treatment may be employed in conjunction with surgery, but results are not as good as when stress incontinence exists alone.

Selection of patients for surgical procedures depends on the diagnosis and on the condition of the patient. The frailty of the patient, the condition of the tissues, and the state of nutrition bear on the ability to heal. The severity of symptoms must be considered in relation to the risk the patient must undertake for their surgical correction. Finally, such factors as the durability of the treatment and the incidence of complications must also be considered in choosing a treatment option.

Behavioral Techniques

Behavioral techniques increase the patient's awareness of the lower urinary tract and environment and can enhance control of detrusor and pelvic muscular function. Such techniques are participatory, relatively noninvasive, and generally free of side effects and do not limit future options. They do require time, effort, and continued practice. Some patients become dry, while a larger number experience important reduction of wetness and others receive no benefit. Those who appear to benefit most are highly motivated individuals without cognitive deficits. Men and women with stress and urge incontinence have benefited, whereas patients with severe sphincter damage (such as in patients with constant leakage after radical prostatectomy) generally do not benefit.

Behavioral techniques should be offered as a choice to patients who are motivated to put in the time and effort and wish to avoid a more invasive procedure. Commonly employed techniques include the following:

- **Pelvic muscle exercises** strengthen the voluntary periurethral and pelvic floor muscles, the contraction of which exerts a closing force on the urethra. These techniques have been emphasized for women with stress incontinence but appear to be useful in men as well. Benefit has been reported in 30% to 90% of women, but criteria for improvement differ among studies. Patients with mild symptoms may improve most. Continued exercise is required for continued benefits.

- **Biofeedback** is a learning technique to exert better voluntary control over urine storage. Biofeedback uses visual or auditory instrumentation to give patients moment-to-moment information on how well they are controlling the sphincter, detrusor, and abdominal muscles. After such training, successful patients typically learn to perform the correct responses relatively automatically. Patients with urinary incontinence are trained to relax the detrusor and abdominal muscles and/or contract the sphincter, depending on the form of incontinence. When used in patients with stress and/or urge incontinence, biofeedback has been shown to result in complete control of incontinence in approximately 20%

to 25% of patients and to provide important improvement in another 30%. There are two caveats: the degree of improvement is variable and long-term follow-up data are not available. It is important to recognize that biofeedback requires sophisticated equipment and training. The benefit of adding biofeedback to pelvic muscle exercise regimens has not been adequately evaluated.

- *Bladder training* instructs patients to void at regular and short intervals, usually hourly during the day, and then at progressively longer intervals of up to 3 hours during a training period of a few to a dozen weeks. Bladder training appears to be effective in reducing the frequency of stress and urge incontinence. Studies have indicated cure rates of 10% to 15% and improvement in the majority of patients.

- *Behavioral techniques in the nursing home.* For the institutionalized elderly, almost any consistent attention to the problem, including bladder training and frequent scheduled checks for dryness, appears to reduce incontinence in at least some patients. Another technique applicable in the nursing home is prompted voiding, in which frequent (every 1 to 2 hours) checks for dryness are made, reminding the patient to void and praising success.

Staging of Treatment

As a general rule, the least invasive or dangerous procedures should be tried first. For many forms of incontinence, behavioral techniques meet this criterion. When behavioral techniques do not achieve the desired result, pharmacologic treatment can be initiated. Clear indications for surgical intervention must be respected, however, and surgical treatment should not be withheld inappropriately. Overflow incontinence due to prostatism and urge incontinence due to carcinoma of the bladder or prostate must be recognized and treated promptly. After having been informed of surgical and nonoperative options, the patient who is a surgical candidate and wants prompt treatment (eg, as in the case of stress incontinence) should be operated on. In patients with mixed incontinence, a combination of surgery, behavioral techniques, and pharmacotherapy may be helpful.

What Management Techniques Are Appropriate When Treatment Is Not Effective or Indicated?

For patients who have not been successfully treated, management plans must be developed to maximize their well-being. Even when permanent improvement is not expected, techniques such as frequent toileting and reminders may be useful in reducing the impact of the patient's incontinence. Careful evaluation of the timing and pattern of incontinence may suggest helpful changes such as bedtime fluid restriction, provision of easier access to toilet facilities, and temporary or permanent arrangements for protection of the patients, their clothing, and the environment.

Currently available modes of protection include absorbent pads or garments, indwelling catheters, and external collection devices such as condom catheters.

Absorbent pads or garments provide comfort and convenience when used temporarily in conjunction with therapy; no method is entirely satisfactory for long-term use. For long-term use with incapacitated patients, absorbent materials are expensive, require personnel time, and can be associated with pressure sores when circumstances prevent meticulous attention to prompt changes.

For men, external collection devices are less expensive and less time-consuming for patient and care giver, but they are associated with increased incidence of urinary tract infection and other complications. Practical external collection devices for women are not generally available.

Indwelling urethral or suprapubic catheters may be necessary for selected patients, but almost invariably lead to bacteriuria within a few weeks and have been associated with sepsis.

5. What Strategies Are Effective in Improving Public and Professional Knowledge About Urinary Incontinence?—There have been limited efforts to inform the public and professionals about urinary incontinence. The effectiveness of these strategies has not been evaluated. Education about incontinence, therefore, must rely on methods that have been used in other areas of health education. Effective strategies to improve public and professional awareness need to be developed, implemented, and evaluated.

Negative societal attitudes about urinary incontinence have been a barrier to increasing public and professional knowledge. The scientific study of incontinence and the dissemination of research findings will help professionals and laypersons realize that loss of incontinence need not be a condition that is inevitable or shameful.

Strategies for Improving Public Knowledge

Providing accurate information on the management of incontinence to persons with this problem and their families is a challenging and important task. Studies suggest that only half of the people with incontinence report their condition to a physician. Strategies that will reach the largest number of people will be effective in encouraging them to seek professional help. These include informative newspaper and magazine articles, radio and television programs, and special educational programs in senior centers.

One innovative suggestion that deserves consideration is the mandatory labeling of all absorbent products, informing the public that persistent urinary incontinence should be evaluated and that effective treatments are available.

Strategies for Improving Professional Knowledge

There is an urgent need to educate professionals and paraprofessionals about urinary incontinence.

First and foremost, information on urinary incontinence should be included in the core curricula of undergraduate and graduate professional schools. Schools of nursing should consider the feasibility of educating specialists on incontinence care, who can serve as expert

advisors to health care professionals.

To increase practitioners' knowledge of this important condition, continuing education courses focusing on the types of incontinence and appropriate diagnostic measures and treatment should be offered. Professionals most likely to provide care to people with incontinence should be encouraged to attend these courses.

Education on the topic of urinary incontinence should also be a part of the training programs for paraprofessional students such as licensed vocational nurses, nurse's aides, and auxiliary workers in the community. Because urinary incontinence is a problem of great magnitude in long-term-care settings, special emphasis should be placed on educating nurse's aides.

Last, coordinated care for people with incontinence will be facilitated by encouraging alliances among all professionals responsible for caring for people with incontinence.

6. What Are the Needs for Future Research Related to Urinary Incontinence?—The Consensus Development Conference on Urinary Incontinence in Adults has provided an overview of current knowledge on the etiology, pathophysiology, sequelae, and management of this prevalent clinical problem. Although information on incontinence is increasing, this field has long been neglected, and numerous gaps exist in our knowledge. While many controversies were addressed, numerous questions were identified that await answers and thus serve as the focus for future research directions. These issues will require the collaborative input of investigators from the spectrum of relevant disciplines and the rigorous application of appropriate research principles.

Directions for future research include the following:

- Basic research on the mechanisms underlying the etiology, exacerbation, and response to treatment of specific forms of urinary incontinence and urgency.
- Epidemiologic studies with emphasis on elucidation of risk factors for development of urinary incontinence, its occurrence in specific populations (particularly men

and nonwhites), and the natural history of the various clinical and physiological subtypes.

- Studies of strategies to prevent urinary incontinence.
- Randomized clinical trials, including longitudinal studies in well-specified populations, of algorithms for the systematic assessment of patients with incontinence and of specific behavioral, pharmacologic, and surgical treatment, either alone or in combination.
- Development of new therapies, including pharmacologic agents with greater specificity for the urinary tract and new behavioral and surgical strategies and other innovative techniques, including electrical stimulation.

Conclusions

- Urinary incontinence is very common among older Americans and is epidemic in nursing homes.
- Urinary incontinence costs Americans more than \$10 billion each year.
- Urinary incontinence is not part of normal aging, but age-related changes predispose to its occurrence.
- Urinary incontinence leads to stigmatization and social isolation.
- Of the 10 million Americans with urinary incontinence, more than half have had no evaluation or treatment.
- Contrary to public opinion, most cases of urinary incontinence can be cured or improved.
- Every person with urinary incontinence is entitled to evaluation and consideration for treatment.
- Most health care professionals ignore urinary incontinence and do not provide adequate diagnosis and treatment.
- Inadequate nursing home staffing prohibits proper treatment and contributes to the neglect of nursing home residents.
- Medical and nursing education neglects urinary incontinence. Curriculum development is urgent.
- A major research initiative is required to improve assessment and treatment for Americans with urinary incontinence.

Members of the Consensus Development Panel were:

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- George A. Kaplan, PhD**, Chief, Human Population Laboratory, California Department of Health Services, Berkeley
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The conference was sponsored by the National Institute on Aging, T. Franklin Williams, MD, Director; the Office of Medical Applications of Research, John H. Ferguson, MD, Director; the National Center for Nursing Research, Ada Sue Hinshaw, PhD, RN, Director; the National Institute of Diabetes and Digestive and Kidney Diseases, Phillip Gordon, MD, Director; the National Institute of Neurological Disorders and Stroke, Murray Goldstein, DO, MPH, Director; and the Veterans Administration, Thomas K. Turnage, Administrator of Veterans Affairs.

50 Years Ago From the *Journal of the Connecticut State Medical Society* September 1939

Medical Air Raid Preparations in England

C. W. GOFF, M.D., F.A.C.S.

Hartford, CT

The British Empire, particularly England and Scotland are aroused. The past three months have witnessed a unique development in national preparation for defensive war, based on technocracy. Every arm for home protection has become of vital importance to the Englishman. From experiences in Spain, Abyssinia, China and Albania have come strategic data on which a defense can be built against the barbaric though modern air raids.

Among the many important factors there appears, near the top, the necessary medical preparations on a tremendous scale not appreciated by the average citizen. As an eye witness during the past few weeks, the author was able to gain first hand information on the vastness and comprehensiveness of these "Air Raid Preparations" in the British Isles. Authorities state that 15 minutes from the time raiding bombers reach the channel they will be over London.

As the liner approached Southampton, the numerous navy patrol boats put in their silent, ominous appearance. As each glided past, the lookout, no doubt, recorded all activities of the many nationals passing through the channel. These blue gray war weapons were in greater numbers than observed on other visits to the Island Kingdom. Many planes constantly passed over head as the craft entered the harbor. The customs were particularly

strict with police officers in profusion about the pier. Probably the current Irish terrorism in England might account for the Bobbies in such numbers. The boat train, on the way to London, passed through a number of localities where many planes were housed or under construction. Hangars were camouflaged and buildings scattered rather than grouped.

On reaching the metropolis of London, huge signs greeted the eye — "WE'VE GOT TO BE PREPARED" and "NATIONAL DEFENSE — IT'S UP TO YOU" — war slogans of 20 odd years ago. Nelson's monument, the delight of every English schoolboy, carries on its tall column a blazing sign — "IT'S UP TO YOU." Every theater, cafe or pub has stacks of leaflets calling on the citizens to offer themselves for voluntary auxiliary work — driving ambulances for the women — blood donors, fire fighters, patrols or balloon handlers for the men. On corners are street signs — "TO THE TRENCHES." Each week, through the mail, the people receive pamphlets containing instructions on rendering homes gas proof; how to build a bomb proof shelter; what to do in case of a raid, fire or muster. Housewives are advised to lay in a two weeks' extra supply of canned stuff "because you

(continued on page 549)

Physician-Owned HMO Off to a Good Start

PAUL TARINI

M.D. Health Nets Profit Earlier than Expected

OFFICIALS at M.D. Health Plan in Connecticut are proud of their HMO.

Less than two years old, the Connecticut State Medical Society-sponsored, physician-owned managed care plan just registered its first quarter in the black. It is ahead of its projected enrollment. In fact, M.D. Health may be the country's only state society-sponsored, physician-owned health maintenance organization—an admittedly tiny genre — that has shown any kind of profit.

For the quarter ending 31 March, M.D. Health, an independent practice association-model HMO, made \$196,168 as opposed to the \$26,335 they projected they would lose. And enrollment was 13,796—up from the projected 12,017 and a 70% increase over the previous quarter. It is the ninth largest HMO in Connecticut, in a field of 12.

A handful of state societies have tried to sponsor physician-owned HMOs. West Virginia's plan never got off the ground; in Georgia, Mississippi and Tennessee, the plans folded; Delaware sold its plan to a private company. Only South Dakota's DAKOTACARE is operating. DAKOTACARE switched to for-profit status at the end of 1988 and with more than 28,000 enrollees, they hope to show their first profit during 1989.

M.D. Health's early success is reflected in their self appraisal. "Our overall approach may be a methodology that may be the future of health care," says Vincent Catrini, MD, the vice chairman and a practicing cardiovascular and thoracic surgeon.

The physicians who pushed for M.D. Health did so in response to trends they saw developing. "We were losing sovereignty and losing control over making independent decisions on our patients," says William A. Whalen, MD, the plan's chairman and a practicing general surgeon.

So they adopted what they think is a best-of-all-possible-worlds philosophy and began M.D. Health. "Most physicians recognized that [managed care plans] are here to stay," says Guy W. Van Syckle, MD, the



Growing in Connecticut

CEO Doug Hayward (left) and Medical Director Guy W. Van Syckle, M.D., lead the young-but-growing M.D. Health, the Connecticut State Medical Society-sponsored, physician-owned managed care plan.

medical director and a radiologist. "No one wants to be told how to practice...not by a vice president in finance. What we're trying to do is generate practice patterns that are being conceived by your own colleagues, that are peer driven."

M.D. Health took national data on practice patterns and costs, modified them for Connecticut's higher percentage of specialists and began to apply them to physicians. They found that 85% of participating physicians were practicing within an acceptable range and another 10% were able to modify their behavior, says Dr. Van Syckle. "Most physicians will respond to data which demonstrate that their practice pattern is significantly different from their colleagues'," he says.

At M.D. Health, they also scrutinize outpatient care patterns. "If they've developed protocols for ambulatory care, then they're way ahead of a lot of people," says Lynn Dowling, a private managed care consultant.

When screening kicks out an oddity, Dr. Van Syckle will call the physician personally to discuss it. "It's simply not appropriate for people who have not taken care of patients" to discuss procedure with physicians, he says. "The discussion will be facilitated by talking to peers."

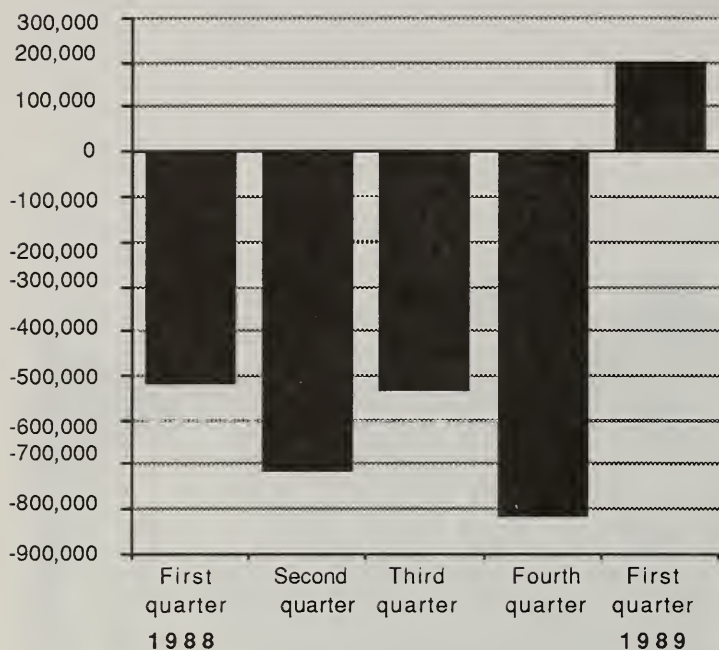
Dr. Van Syckle says the approach maintains harmony

PAUL TARINI, Staff Member, *American Medical News*.

Reprinted with permission from *American Medical News*, July, 1989.

while it helps to contain costs. "We want to be as helpful as we can, but we still have a business to run... We can't give away the store," he says.

The approach, Dr. Catrini feels, may have solved the equation of cost containment and quality of care. "We've put it up in order to protect our interest in directing the course of medicine in this country," he says. "We hope that if this works well, it will be a light for other states."



The Connecticut State Medical Society-sponsored, MD-managed HMO recently enjoyed its first quarter in the black, out-performing other MD-owned plans.

WITH JUST UNDER 15,000 enrollees at the end of April, M.D. Health remains a long way from being a beacon. As HMOs go, this one is still very small. Nevertheless, it is hard to deny the success. "It is rare to go into the black that fast," says Ronald Hurst, executive vice president of the American Medical Care and Review Assn. "It's very difficult to go into the black below 50,000."

M.D. Health was able to return 100% of the physician's withhold last year, something Patrick Carolan, MD, the IPA president views with cautious optimism. "Most HMOs starting out, work efficiently because they don't have great numbers," he says. "The thing that preserves the withhold is the appropriate utilization of care."

MDs from around the state have been conscientious about utilization patterns, Dr. Carolan says. "The people who are setting up the utilization are actively practicing physicians from all over the state, it's not simply a bottom-line decision," he says. "It's a company of doctors working with doctors."

That emphasis has attracted physicians throughout the state. The IPA has just more than 2,100 members, most of whom had to buy equity shares in M.D. Health for \$4,000 to join. The plan recently began allowing physicians to join the IPA by paying only an annual fee.

The hope is that physicians who balked at the higher price will pay the participation fee, thus deepening M.D. Health's area coverage.

Obviously, being physician-friendly is an insufficient guarantor of success. M.D. Health has had to hustle. "As the late comer and the small guy they're pushing hard to be the innovator and the creator to survive," says Ralph Pollock, president of the Connecticut Business Coalition on Health.

M.D. Health is branching out. It has spun off a preferred provider organization, called MedChoice, and is considering other products, including disability and life insurance. "No HMO can survive without diversification," Dr. Whalen says.

M.D. Health's diversification has been precocious. Only 30% of provider-owned (physician, hospital, or physician and hospital) plans that are more than 3 years old offer PPO options, says Susan Pisano, spokeswoman for the Group Health Assn. of American. In the New England, it's below 17%.

Part of M.D. Health's success can be attributed to being in the right place at the right time. In 1987, Connecticut was ripe for a statewide HMO. Only 9% of the state's residents were enrolled in HMOs, none of the existing plans had a statewide provider network. And the small state's population is concentrated around urban centers, so it is easy to service.

Currently, about 18% of Connecticut residents belong to HMOs, says Michael Herbert, treasurer of the AMCRA and president of Physicians Health Service of Connecticut Inc., one of M.D. Health's competitors.

Herbert says "the potential upside in the market is very great. HMOs in Connecticut last year grew about 20%." The other story in Connecticut, Herbert says, is the losses HMOs incurred last year. For instance, three plans owned by Blue Cross lost a total of \$24 million. M.D. Health lost more than \$2.5 million.

Physicians Health, the perennial winner in the area with 25 consecutive profitable quarters, also does business in Westchester County, N.Y. The company is physician controlled, though not wholly M.D.-owned, and its strength lies mainly in southern Connecticut.

Herbert wonders about M.D. Health's staying power. "It's been a price competitive market for a couple of years now, most HMOs are deep-pocketed," he says. "I question within the next couple of years whether there will be any HMO in Connecticut that does not have deep pockets or has reached a certain level of maturity" of enrollment of about 50,000 or more.

Herbert wonders if M.D. Health is struggling to meet a state operating requirement of \$1 million in net equity. "They have already gone through \$6 million [in equity investments by the physicians] to get it up and running."

To raise the \$1 million, which was required after M.D. Health got started, the plan levied an assessment on its



Solving the costs, care equation

MDs control care at M.D. Health, says vice-chairman Vincent Catrini, MD (left, with patient).

members and the Connecticut State Medical Society co-signed a \$600,000 loan, says Morton Silberstein, MD, the plan's treasurer and a practicing psychiatrist.

M.D. Health currently has a net equity of \$1.2 million, says Doug Hayward, the CEO. "It's a little tight, but it's there," he says.

Herbert then looks at the recent round of premium hikes. Most plans in Connecticut went up 25% to 30%; M.D. Health held theirs to 19.4%. "We sit around with our financial people and look at their rates and say, 'how can they do that?'"

Hayward answers that their hike was essentially a cost-of-living hike, to cover projected increases in medical costs in Connecticut. Older plans, Hayward says, have to cover those increases, plus make up part of the losses from previous years. M.D. Health, being so young, does not have those accumulated losses, he said.

Beyond that, it helps that M.D. Health is not motivated solely by profit. "The return to M.D. Health Plan investors is that we can continue to practice medicine in the traditional practice," Dr. Catrini says.

Herbert also points out that M.D. Health has almost no budget for marketing or public relations this year. "It says to me that they may be sacrificing the long term for the short term," he says. "If they're not doing it to stay above the net equity requirement, then I'm puzzled."

Hayward says the company made a strategic decision. An HMO is a two-step sale. The first is to employers and once that sale is made, he says, you have immediate access to the employees. "We decided to develop more personal contacts with employers."

That sales strategy involves reaching out to licensed insurance brokers in the state. "The brokers acted as sales people that we didn't have to pay," says Dr. Silberstein.

M.D. HEALTH provides training seminars on the HMO concept, puts out a broker newsletter and holds monthly meetings for the 250 brokers who sell M.D. Health. "What they gave us was an inside track to owners and the CEOs of small and large corporations," says Pasquale Nuzzolillo, M.D. Health's director of agent development.

M.D. Health thought the broker network was important enough to make Nuzzolillo the third hired. "I was working off a window sill," he says.

Using brokers is rare. "People generally ignore brokers," says Dowling. "These are the guys who sell the product. I find that highly unusual for a physician-oriented plan to appreciate the broker community."

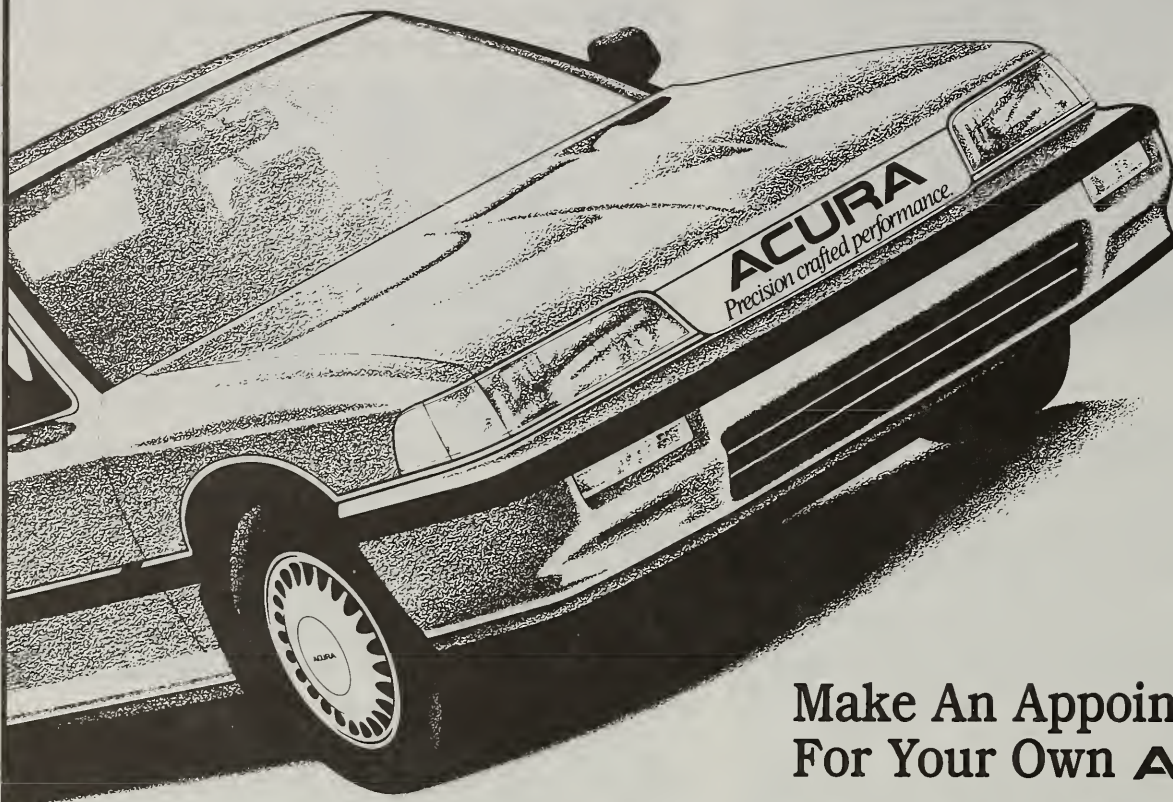
M.D. Health has exploited niches. Historically, HMOs avoided small businesses. The payoff wasn't big and small business employees tended to use more services. However, says CEO Hayward, "technological change in the past 10 years has increased productivity per worker so that most growth is in smaller businesses." So the market merited examination.

M.D. Health officials noticed that with increased productivity came usage patterns closer to the larger market. So M.D. Health went after small businesses with a vengeance.

MedChoice, their PPO, is an open-ended option for employers who self-insure. One facet of MedChoice is that its premiums are keyed to eight categories based on age and sex. MedChoice was initially offered in just one region of the state. After gauging its success (the plan has 20 employers), it is now offered statewide. And M.D. Health just floated a proposal to one of the state's employers offering a risk sharing arrangement with MedChoice.

All of M.D. Health's innovations are aimed at protecting an old idea. "The physician and patient should be a duo that is minimally encumbered by extraneous forces," says Dr. Catrini. "Part of what we're doing is trying to maintain that delivery of care. If physicians can hold on and maintain their integrity, they're going to win the battle in the long run. We've got to win, because we're the deliverers of health care."

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Medical Care Costs: No Easy Answer

Last month an editorial appeared in the New Haven Register headlined "Health Care Cost Crisis Grows," and opened with:

"The American health care system is wasteful, poorly regulated and motivated as much by private profit as the public good."

The writer then went on to note that while we spend more than any other country, the United States has "...no demonstrably superior standard of care," and our "...physicians remain largely free of oversight by the public. They charge what they please, perform unnecessary tests and expensive, high-profit and needless surgeries."

The editorial writer concluded: "Only when the general public begins to feel the costs of medical inefficiency in their own pocketbooks, instead of buried in the cost of goods they buy, will we find the political will to control the medical establishment's wanton waste."

Timothy B. Norbeck, Executive Director of the Connecticut State Medical Society wrote a response to the Register, only a portion of which was published. His complete response follows:

Your August 13 *Register* editorial ("Health Care Cost Crisis Grows") is irresponsible, misleading and wrong. No one questions the concern shared by everyone, including the medical profession, over health care costs, but to lay the blame for it on waste and inefficiency is an outrage.

An ever-improving medical technology, the best in the world, increasing access (although that remains a problem), inflation and a growing utilization of services are the main reasons for escalating health care costs. Thanks in part to good care, our people live longer, and the Medicare enrollee list swells (happily!) by more than 500,000 persons per year, and more frail elderly survive longer and require additional costly services. That's *good* news, not bad!

Every poll which addresses the issue of new technology indicates that the American public wants *more* funds - not less - spent on medical technology. Americans possess a fierce desire and a tenacity to enjoy the best medical care available, and to live as long as possible even in spite of unhealthy life styles - and may the costs be damned. Those costs now are and will continue to be incredible, with three million drug abusers at large, 18 million alcohol abusers on our turnpikes, 55 million tobacco abusers causing 1000 lingering deaths each *day*, and the nearly one million *new* cases of venereal disease every year.

Editorials are expressions of personal opinion and do not necessarily reflect the policies of CSMS.

Connecticut Medicine does not hold itself responsible for statements made by any contributor.

Waiting in the wings are the crises of long-term care, homelessness, Alzheimer's disease, the uninsured and underinsured, pregnant women lacking or simply neglecting prenatal care, and the burgeoning tragedy of AIDS. It has become too easy for captious critics to overlook these realities and crassly lay the blame for increased medical costs at the feet of physicians, who must be the messengers for the bad news. It's like blaming the police for more crime.

The *Register* suggestion that inefficiency, waste, and a lack of accountability are the key factors in escalating health costs simply doesn't wash. It does illustrate, however, the unfortunate truism once expressed by Eugene McCarthy that "anything repeated three times in Washington becomes a fact."

The *real* fact is that physicians' services, which account for about 20% of all health care expenditures, (a number, incidentally, which has remained constant since 1950,) are indeed closely scrutinized. Just look at the record. Physicians are subject to review from state licensure agencies, medical societies, specialty boards, hospital credentialing committees, liability insurance company underwriting and claims review panels, hospital quality assurance and utilization review departments, hospital committees for morbidity, mortality, tumor and tissue review, —not to mention the regulatory scrutiny of federal agencies such as Medicare and the Drug Enforcement Agency and of state agencies regulating prescriptions, office lab and x-ray facilities, Medicaid, and other matters. What other profession is subject to such scrutiny?

Why can't we put our collective energies together in a constructive way to see what can be done to address rising costs instead of denigrating a system, although imperfect, which is working so well for so many? Yes, we must assure better access for uninsured Americans, but we do have the best system yet devised and it's getting better.

Having gratuitously claimed that there is "no demonstrably superior standard of care" in this country as compared to others, perhaps the *Register* ought to explain why patients travel to the United States from all over the world for our quality, high-technology medical care. As comedian Jack Paar once noted, "*Immigration* is the sincerest form of flattery." The traffic is *not* moving in the opposite direction!

As a perfect example of the best of American technology, New Jerseyite Arlene Keene recently received seven artificial replacement joints: two shoulders, two hips, two knees and one ankle. Is the *Register* suggesting that these procedures cost too much, and that this real-life bionic woman should never have danced at her daughter's wedding?

Reinventing the Wheel

The Connecticut Business Coalition on Health and the Connecticut Health Care Purchasing Organization

All CSMS members, whether or not they are among the participating physicians in M.D. Health Plan, our sponsored managed care system, should be aware of the current aims of the Connecticut Business Coalition on Health, founded in Hartford under the direction of health planner Ralph Pollock, its president. It has been reported that the Coalition, comprising 42 area employer groups, is actively engaged in formulating its own "Connecticut Health Care Purchasing Organization," a new fourth-generation of preferred provider organization (PPO). The intent is to start in the Hartford area, and then spread out statewide, ultimately serving as a national model.

The term "health care purchasing organization" (HCPO) means a *buyer*-sponsored PPO-type fiscal intermediary directly accountable only to such sponsors. Recently, some self-insured employers, though multi-employer trust funds or individually through business coalitions or unit trust funds, have created their own PPOs in order to assert themselves directly in cost containment efforts involving their employees' medical care.

The Coalition's leadership believes the the Connecticut HCPO will give to employers what they seek: a direct voice and stake in their fiscal intermediary, local control, an opportunity to treat health costs like any other cost of doing business, and continual monitoring of HCPO performance through direct access to detailed, comparative healthcare data not now being made available by their other health plans. Of more interest are four additional reasons why these employers would seek to create their own HCPO: leverage for negotiating more favorable arrangements with physicians, other providers, and other fiscal intermediaries; getting an added option without having to break an existing relationship with a current insurer, health plan, or third party administrator (TPA); having a mechanism by which to offer information and direction to employees about accessing more cost-effective healthcare options and providers; and the ability as a group to revise the structure of the HCPO.

Besides establishing direct control and reducing both ambulatory and hospital utilization and claims costs, these 42 companies have the added goal of becoming recognized as important clients of providers and intermediaries alike, and indeed they are. If all these goals sound threatening to physicians and institutional providers, it must be kept in mind that employers no more want their businesses to be controlled by insurance companies or other third party payers than physicians or hospitals do.

Ironically, there is already one place where these and like-minded employers can find *all* the features that they seek in the HCPO being formulated by CBCH. M.D. Enterprises of Connecticut, Inc., which operates the statewide M.D. Health Plan HMO, *already* offers exactly such a fully self-funded employer-based PPO option in conjunction with Stirling and Stirling, Inc., a Connecticut-based third party administrator (TPA). It is called Employer Medical Choice Health Plan ("MeDchoice"). It combines all the elements necessary to administer an employer-based self-funded health benefits program with the cost-containment attributes required for successful managed care programs.

Moreover, MeDchoice is flexible, being adaptable to any company's existing actuarial arrangements. For example, if the company does not have an underwriter, MeDchoice can provide one through its association with North American Life & Casualty, a major stop-loss company. MeDchoice can administer the entire program; all necessary systems and staff are accessible. Its state-of-the-art MIS system can provide unique data reporting designed to meet a company's needs. In addition, benefits design, eligibility screening, customer service, claim adjudication, provider payment, and even COB services are on line. Physician-driven quality and utilization peer monitoring is applied not only to hospital care, but beginning this month, to ambulatory care as well, and includes hospital precertification on all non-emergency admissions, case management by concurrent review, and retrospective review of all claims for medical appropriateness. Finally, MeDchoice can provide COBRA administration and other reporting services required by a company from time to time.

But unlike other alternative systems, the MeDchoice managed care program provides comprehensive cost-effective benefits *without* fragmenting our state's excellent delivery system. Our 2,200-physician and 36-hospital statewide network has proven convenient to employees; for their companies, it's one-stop shopping.

The Connecticut State Medical Society formed MDEC and M.D. Health Plan to be totally owned and directed by physicians, and with a mandate: to offer companies cost-effective, quality patient care in stable physician-patient relationships free of inappropriate nonmedical interference. As its owners, M.D. Health Plan's doctors have a stake in its success and that of its alternative delivery system products like MeDchoice; thus they have been willing to cooperate in its peer-driven cost-effectiveness systems. And doctors know better than anyone that the most cost-effective patient care also just happens to be patient care of optimal quality and appropriateness.

Moreover, MDHP was designed to achieve unprecedented cost-savings for employers by *eliminating* the costly and unproductive third-party-payer middleman interposed between the provider and the purchaser of medical care. Nowhere does this mutually advantageous

design objective come closer to complete fulfillment than it does in MeDchoice, which teams employers with physicians in a common effort to make sure that precious health care dollars go to buy health care for employees, not red tape.

Of course, employers cannot, and for the most part they do not begrudge their employees the same fine medical care they expect and demand for themselves and their loved ones. At least in this state, there is now no reason, however, why employers should pay more than it actually costs for the provision and payment of such care. M.D. Health Plan and MeDchoice are working! Not yet in the third year of operation, they already provide medical care for over 25,000 members statewide

on the principle that nothing but trust should ever come between patients and their doctors.

M.D. Enterprises has worked hard to bridge that chasm of old misconceptions which has separated physicians and employers for too long. Hundreds of contracting employer groups can attest to positive performance as promised. Why should anyone now want to reinvent this wheel when there is already in place via *MeDchoice* all the exact program ingredients sought by everyone concerned?

Robert J. Brunell, M.A.

Mr. Brunell is CSMS Director of Scientific Affairs, and has staffed CSMS development committees for CSMS-IPA, M.D. Health Plan, and CMIC.

MEDICAL AIR RAID PREPARATIONS IN ENGLAND

(continued from page 542)

might find it difficult to obtain food if an emergency should arise."

What is this emergency? The Englishman is being aroused to a danger that the government believes eminent. Through unusually sensible channels, the minds of Mr. and Mrs. Citizen are being prepared for the worst. Everyone is familiar with the new conscription, the huge armaments under construction and the constantly changing international situation. The press is filled with these bits of news but through more subtle ways the English are stirred to expect anything. This is a highly satisfactory state of mind for the government. Thus is created a background which will stand any kind of shock, such as greater concessions to the aggressor nations or even war. Everyone talks of the situation, constantly repeating the same phrases, "We will be next," "We have just 15 minutes" or "Now we are dealing with a crazed man." Of course, the theaters are crowded as usual; traffic goes on just the same. No one postpones his holiday and the travel people complain bitterly that the American tourist traffic has fallen off over 50 per cent.

Mr. Elliott, the Minister of Health in Mr. Chamberlain's cabinet, has divided the country into medical districts with every physician assigned to a post in the scheme of affairs. This plan calls for each physician to present himself at a pre-arranged station immediately upon the creation of an emergency. Since two thirds of the population of every large urban area, during or immediately after the first air raid, will be transported to pre-arranged quarters in the surrounding country, medical services must accompany them. All private practice of medicine will cease to exist and all physicians will become employees of the government either on a full or part time basis. The

scale of salaries to be received has been determined, beginning in the highest brackets with \$7000 down to physicians who will receive \$2.00 an hour on a part time basis. The average full time physician will receive about \$3200 per year. All specialists have been assigned to man hospitals or large concentrations of the evacuated two thirds of the people. Every metropolitan hospital becomes an emergency hospital. Wooden hutments, camp hospitals, private buildings and tent towns are being erected in the country surrounding large cities. When the warning sirens scream, all transportation, by prearrangement, will concentrate at certain points to evacuate hospitals, institutions, schools and the like. All old people, all children and many of their mothers make up two thirds that must be evacuated. There will be left in the large cities only the necessary workers to man public utilities, essential offices, functions of the government, food handlers, fire fighters and all important medical personnel to care for the casualties incidental to the raid.

With two thirds of the metropolitan population thus carried out of the cities and scattered over the country side, the remaining one third will eventually have sufficient protection from falling debris and bursting fragments within the concrete trenches that are now under construction in all of the parks. London is farthest ahead in this regard with every park sprouting stone burrows. Protection is, however, not afforded from direct hits. Casualties will be inevitable. First aid will be of tremendous importance because of the terrific effect of the modern aerial bombs.

During the author's visit to Edinburgh, the first meeting was held of all physicians, numbering some 200 to 300 from the community. Sir John Fraser, Professor of

Surgery at Edinburgh University, addressed the meeting on the expected casualties and technic of first aid. The seriousness with which each physician conducted himself was striking. Sir John described the expected intense shock from hemorrhage produced by the bursting of a modern aerial bomb whose casing would be marked off in small squares, permitting a veritable hail of small, sharp fragments. These will produce multiple deep wounds, any one of which might sever an important artery. A new tourniquet, designed for rapid application and which is to be applied as near the source of hemorrhage as possible, was discussed. Because of the tremendous loss of blood expected and the universally acknowledged use of blood as the best treatment in shock, registered blood donors become a vital part in shock treatment. This would be administered only in hospitals.

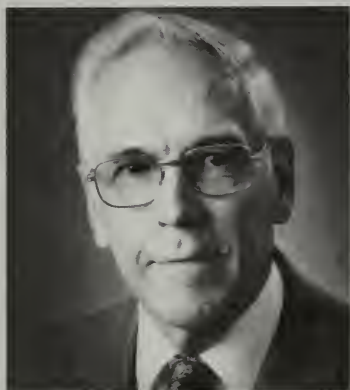
The new gases and their effects were discussed and everyone was cautioned to stow his gas mask with care. A particularly startling effect of a new high explosive bomb was explained. This bomb can produce death by concussion, without wounding, at a distance of 400 yards. The overwhelming concussion sends the air and gases under tremendous pressure into the respiratory tract and produces death by multiple hemorrhages within the lungs and sinuses. Similar meetings are being held weekly all over the British Isles, instructing physicians in their anticipated duties and keeping them informed of governmental preparations.

The reality of an air raid was demonstrated to the

author on two occasions, one in Edinburgh and again in Manchester, during prearranged trial "black outs." Every light was turned out and the patrol Bobbies wore luminous breast plates and gloves. Small ultra violet lights adorned corners for traffic control. It is surprising how gruesome a vast city becomes when it is completely darkened and the sky is streaked with shafts from search light batteries. These lights are manned constantly in two zones. The outer zone about a city having a range of 25 miles, selects approaching planes and the inner zone of lights spots the planes for anti-aircraft gunners. Balloon barrages will be used in London to keep the invading planes at a high altitude.

What becomes of private medical practice? Legislation will soon be passed by Parliament to take care of indemnifying the private citizen against loss of property. No indemnification, however, will be forth coming for the physician who loses his private practice. As long as the emergency exists, people will be dispersed and private practices will be non-existing. The physicians will probably never be able again to collect their former practices and accordingly will be dependent upon governmental office for their livelihood. But people will have become accustomed to governmental protection. Their medical care will be free. A new economy in medicine will come to exist, which is already causing misgivings in the minds of medical leaders in England.

It's Our Turn



Health Care economists and others have predicted that once hospital costs had been controlled a major attack would be made on physicians' fees. The Congress has begun the process and, no doubt, major legislation will be passed this year. Since the administration strongly supports this effort, we can expect significant changes in Medicare Part B payments.

Already over the past few years your practices have been impacted by multiple changes in the Medicare program administered by the Health Care Financing Administration. Both volume of services and unit price per service have been targets. In an effort to control the volume of services, HCFA has among other things imposed preadmission certification, one day surgery for selected procedures, same day admission for others and retrospective denials. Unit prices were cut for certain so-called "overpriced" procedures and other allowances reduced. These changes, major as they are to us, have not brought down payments to physicians to the extent demanded by Congressional budget makers.

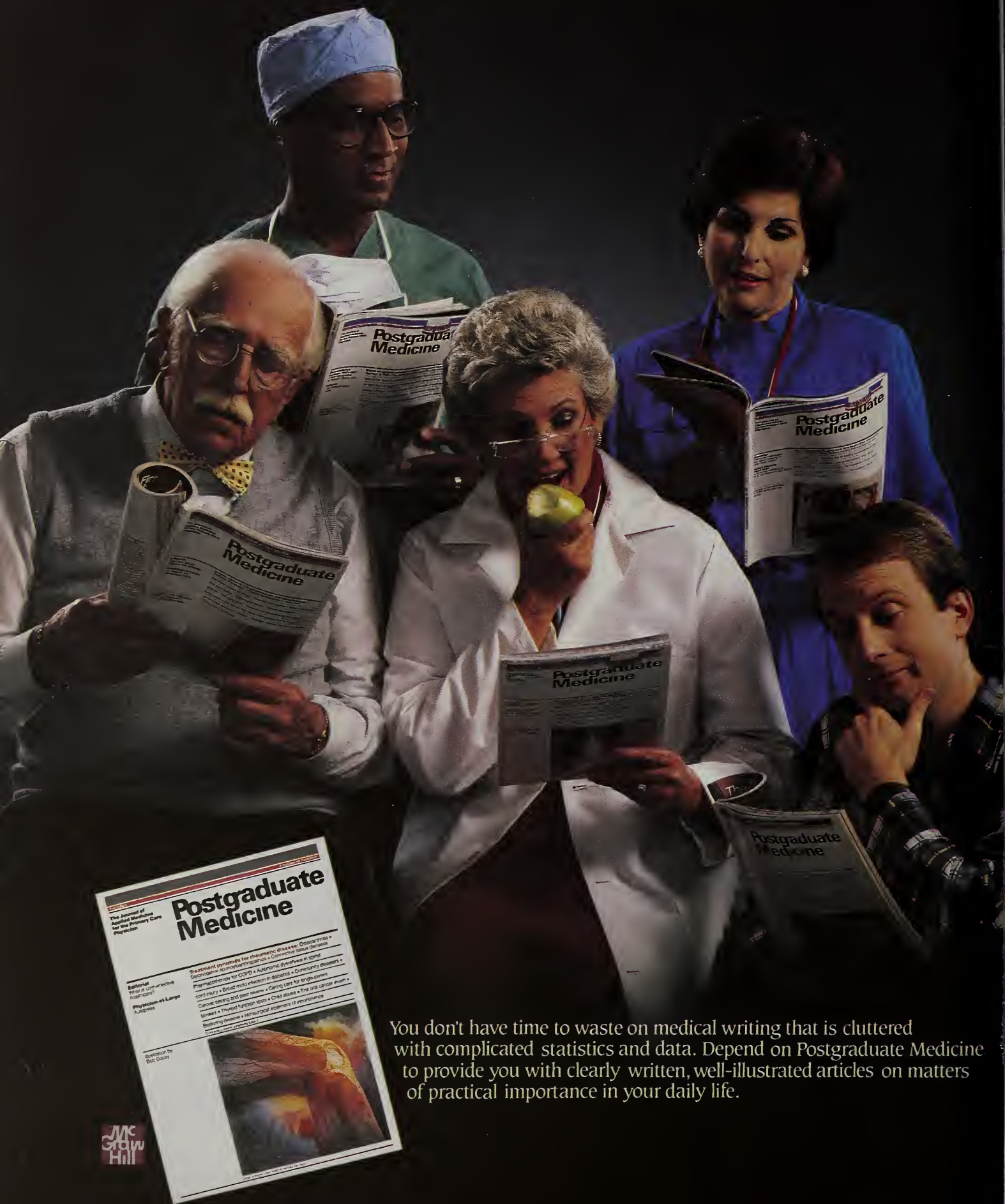
It was inevitable then that physicians fees would have to be reduced to match Medicare Part B expenditure projections. The Hsaio report, released last Summer, which proposed a Resource Based Relative Value Scale (RBRVS), appeared to be a way of revising the traditional physician fee structure to accomplish this. There was immediate criticism of the Hsaio report. The recommendations reducing surgical fees and increasing payments to primary care physicians were not well received. Other concerns related to the incompleteness of the study of surgical specialties, the inadequacy of allowances for pathology and psychiatry, the matter of balance billing, and the way geographic differences in fees (rural vs urban) would be managed. The AMA House of Delegates in December 1988 accepted the concept with a commitment to help resolve the disputed issues.

As the Physician Payment Review Commission (PPRC), to whom the Hsaio report was submitted and from whom the Congress was awaiting recommendations, began to study this report, it received many suggestions. In February 1989 the American College of Surgeons proposed to the commission that an expenditure target for surgery be implemented, practice guidelines be established, and a Medicare fee schedule based equally on supply-side and demand-side be considered. These concepts differed dramatically from those adopted by the AMA to whom expenditures targets are another name for expenditure caps which, most certainly, will lead to rationing. These two large medical organizations, at odds with one another, testified and lobbied in Washington along with a dozen other national specialty organizations. Members of Congress were exposed to a confusing variety of concerns and concepts from physicians. There was no common message from the medical profession.

What has the Congress been doing? The House Ways and Means Committee, free to choose among the various proposals and always able to find some medical group to support each, wrote a bill to their liking. Whether it is good for physicians is a matter of opinion. The bill implementing a new resource based fee schedule with expenditure targets and other provisions was approved. An amendment to remove expenditure targets, offered by Representative Nancy Johnson of New Britain was defeated by the Committee. Subsequently, the House Energy and Commerce Committee approved a similar bill without expenditure targets. The Senate Finance Committee has yet to act. The final form of the legislation and the date for implementation will be determined later by a House-Senate Conference Committee.

Roger S. Beck, M.D.
President

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And to Teach Them this Art

ROBERT U. MASSEY, M.D.

In 1997 the class that begins medical school this month will be winding up their residencies and starting their forty-year careers in medicine. They will retire in the late 2030s, a century after the end of the Depression and the beginning of World War II. To help them get ready for this long journey we shall be going over the maps and guidebooks of medicine, talking with them about the language, the rules, the people, and the sacred texts. I asked one group how many had heard of William Osler. No one. I expected that, so then asked about Hippocrates. Most had heard of the "Father of Medicine," but when I asked about his time, nobody ventured at first, then timidly a young woman barely audibly suggested, "Sixteenth century?" But there was interest, and most palpably awe and romance, the romance that is the first step to learning. Maybe I had heard of Osler when I began medical school; I am not sure, but I doubt it even though he had died only 22 years earlier.

Do they know that medicine is a calling, that by some inexplicable twist of circumstance they are the elect who have joined a crowd numbering less than 0.3% of the population? A most unusual and special bunch with unique and awful responsibilities, whose members are known everywhere by a special title that commands a priori respect? I believe they do. And they also are quite aware that the profession itself may have failed recently to read its guidebooks, may have strayed from the rules, and forgotten its calling. These new students may not know what *primum non nocere* means; they never learned Latin. But they sense that medicine now seems eagerly to be turning itself into a commercial enterprise while at the same time insisting that nothing has changed; our job is to nurture their discontent with the way things are and discourage them from falling in with fashion, a fashion in no way unique to medicine but rather belonging to the absurdly materialistic era we live in.

Bad doctors are easy to spot: exorbitant fees, sloppy care, inept, incompetent, cruel, insensitive; their likes have been caricatured in literature for 2,500 years, and a few of them are always around. It is the good doctors who cut corners that ought to worry us more: ethical corners, financial corners, letting skills and knowledge

slip, doing the right thing for the wrong reason, doing unacceptable things without knowing, careless, not taking pains. They too have always been around, but it once was easier to do something about them; now the law is on their side, and making a fuss is too much trouble. So we have come to accept them, and their brand of professionalism has become a normal variant.

Advertising and price competition, once considered shamefully unprofessional, are now encouraged by our political masters, even mandated. The regulators delude themselves into believing they can control the quality of our work by regulation while we busily compete for market share on price and by making deals. Recently the antitrust whizzes have tried to do the same thing to the universities, get them to compete on price, never mind the quality.

Meanwhile some doctors are advertising with a vengeance, announcing that they will produce psychologically sound weight loss and treat body image problems. Physician periodicals headline, "Mergers seen more favorably in competitive market," and publish cheerful features about preserving market share in a fiercely competitive climate, of static patient bases, and eroding incomes. I recall an especially worldly clergyman who spoke amiably of his parish families as "paying units."

First year medical students are a great pleasure to those of us who are the more ancient members of the faculty; they see through this medicine mongering and are as shocked and offended by the commercialization of medicine, sometimes politely called monetarization or corporatization, as we are. So are patients and the families of patients: they know that medicine owns a noble tradition that has somehow temporarily gotten misplaced.

A presidential speech writer commented recently that political trends recycle every 15 to 20 years, time for one generation to react against their fathers and discover their grandfathers. And only the other day a corporate executive who is responsible for employee benefits in his company said, speaking of the silly hodge-podge of medical care arrangements now touted as the final solution, "We're probably responsible for all this; it obviously is not working, and we should try to help change it by urging good doctors to take charge of medicine and be responsible for quality." Just straws in the wind.

ROBERT U. MASSEY, M.D., Professor, Division of Humanistic Studies in Medicine, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

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Abortion 1989: Seeking a Delicate Balance

JOSEPH M. HEALEY

THE end of the 1988-89 term of the United States Supreme Court brought the latest in a series of long-awaited opinions dealing with abortion. The case of *Webster v. Reproductive Health Services*¹ represented the third major consideration of Missouri abortion statutes by the United States Supreme Court. In 1976, the Supreme Court reviewed the 1974 statute, upholding three provisions (those dealing with the definition of viability, the consent process, and record keeping), while holding unconstitutional four provisions (the spousal consent provision, the parental consent provision, the prohibition of abortion by amniocentesis, and the requirement to use professional care to preserve the life of the fetus regardless of the stage of pregnancy).² In 1983, the Supreme Court reviewed provisions of the 1979 statute, striking down a requirement that all abortions after twelve weeks be performed in a hospital, but upholding other provisions such as those requiring a pathology report for each abortion and requiring a special consent process for minors.³ The most recent decision, released on July 3, 1989, focusses upon four provisions of the 1986 statute: (1) its preamble setting for the legislative finding that "(t)he life of each human being begins at conception," and that "(u)nborn children have protectable interests in life, health, and well-being"⁴; (2) a prohibition on the use of public facilities or employees to perform abortions; (3) a prohibition on public funding of abortion counseling; (4) the requirement that physicians perform such tests or examinations as would be necessary to determine whether each fetus of twenty weeks' gestation or greater is viable. To no one's surprise, the resulting opinions reflect a bitterly divided Court and a continuing absence of consensus about this issue.

There were five opinions. The division among the justices of the Supreme Court, reflective of the division which exists generally in the United States, can be seen in the following excerpt from the Syllabus of the case:

Rehnquist, C.J. announced the judgment of the Court

JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

and delivered the opinion for a unanimous Court with respect to Part II-C, the opinion of the Court with respect to Parts I, II-A, and II-B, in which White, O'Connor, Scalia, and Kennedy, JJ., joined, and an opinion with respect to Parts II-D and III, in which White and Kennedy, JJ., joined. O'Connor, J., and Scalia, J., filed opinions concurring in part and concurring in the judgment. Blackmun, J., filed an opinion concurring in part and dissenting in part, in which Brennan and Marshall, JJ., joined. Stevens, J., filed an opinion concurring in part and dissenting in part.⁵

Chief Justice Rehnquist, writing for the plurality, argued that the case was properly handled:

The dissent also accuses us, *inter alia*, of cowardice and illegitimacy in dealing with "the most politically divisive domestic legal issue of our time." *Post*, at 23. There is no doubt that our holding today will allow some governmental regulation of abortion that would have been prohibited under the language of cases such as *Colautti v. Franklin*, 439 U.S. 379 (1979), and *Akron v. Akron Center for Reproductive Health, Inc.*, *supra*. But the goal of constitutional adjudication is surely not to remove inexorably "politically divisive" issues from the ambit of the legislative process, whereby the people through their elected representatives deal with matters of concern to them. The goal of constitutional adjudication is to hold true the balance between that which the Constitution puts beyond the reach of the democratic process and that which it does not. We think we have done that today.

Discussion of the *Webster* case will continue in next month's column.

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5. 57LW 5025.
6. 57LW 5031.

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CARDIAC SURGERY IN THE ELDERLY

(Reprinted from *Connecticut Medicine*, December 1988)

To the Editor: The report by Houser and associates on cardiac operations in octogenarians in the October issue of *Connecticut Medicine*¹ adds to the climate of support for the use of these procedures, when indicated, without undue regard to chronologic age. Over a decade ago, the safety of aortic valve replacement in septuagenarians was recognized,² and closed catheter aortic valvuloplasty will not eliminate the need for this operation.³ Both Houser's group and that of Naunheim⁴ have shown good results with still-older patients, and one can envision a time when even a centenarian might be considered a suitable operative candidate, as they already can be for cholecystectomy or mastectomy.⁵ The need for surgical solutions to symptomatic ischemic and valvular heart disease will grow rapidly along with the total pool of aged persons, the large number who are mentally vigorous and systemically healthy, and the critical subset for whom cardiac symptoms are the principal detriment to quality of life, and who have surgically amenable causes. Every primary-care physician who sees adults, and every geriatrician, will encounter such patients. It is vital that the profession recognize the advance in cardiac gerosurgery, lest patients be denied a significant therapeutic modality based on a blanket sense, rather than on analysis of the evolving experience and the particulars of an individual case.

The hazard of emergency cardiac operations in this series is not clear, because the denominator (ie, total number of emergency cardiac operations) is not specified. If it is only the five cases cited in the analysis of deaths, the mortality is 100% and restrictions are justified pending improvements in medical and surgical management. If there were many more, the results may call for further analysis, since the alternative, conservative management, is surely bleak. Inclusion of these data would help practitioners make the best possible clinical decisions with the present state of the art. Meantime, perhaps the best conclusion to draw is not that emergent procedures should be withheld in these patients, but that elective operations are associated with best results and therefore are most clearly justified.

Henry Schneiderman, M.D.,

University of Connecticut Health Center, Farmington

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DRS HOUSER, HASHMI, LEHMANN, AND CHAWLA RESPOND:

To the Editor: Dr. Schneiderman's question regarding emergency cardiac surgery in octogenarians was pertinent. I therefore have divided the 69 octogenarians previously reported¹ into two groups: an emergency group (33 patients), and an elective group (36 patients). The emergency group consists of those patients who required hemodynamic support in the coronary care unit (CCU) prior to cardiac surgery; their operative mortality rate was 24.2% whereas that of the elective group was 5.6% ($P=0.03$).

The following data relate to the emergency group (excluding one patient whose data could not be located). Of five patients with a pre-CCU history of unstable angina and no failure, controlled with intravenous nitroglycerin in the CCU, only one died postoperatively, and that death was secondary to a stroke. Of nine patients who in the CCU had recurrent angina but no congestive failure, all survived their operations, including two patients requiring intra-aortic balloon pump support. On the other hand, seven of 18 patients with congestive failure treated in the CCU preoperatively died following cardiac surgery. Three patients with failure and angina required intra-aortic balloon pump support without endotracheal intubation and survived. Two of six intubated patients without intra-aortic balloon pump support survived. Only one of four patients in congestive heart failure who required both intra-aortic balloon pump support and endotracheal intubation survived.

In summary, an octogenarian who requires cardiac surgery on an elective basis should do well. Even if he requires control of angina without congestive heart failure in the coronary care unit, he certainly has a reasonable chance of survival. However, the octogenarian requiring treatment of heart failure in the coronary care unit preoperatively carries nearly a 40% operative mortality

risk. This mortality risk increases to 67% if endotracheal intubation is required and to 75% if both endotracheal intubation and intra-aortic balloon pump support are needed preoperatively. These data should help the cardiologist and the cardiac surgeon decide where to draw the line on these elderly patients.

Stuart L. Houser, M.D.
Fayyaz H. Hashmi, M.D.
Timothy J. Lehmann, M.D.
Surendra K. Chawla, M.D.

Hartford

1. Houser SL, Hashmi FH, Lehmann TJ, Chawla SK: Cardiac surgery in the octogenarians: Are the risks too high? *Conn Med* 1988;52:579-81.

LYME DISEASE ISSUE

To the Editor: (This letter was received by Dr. Matthew L. Carter guest editor for the June issue of Connecticut Medicine).

Many thanks for the copy of the June issue of CONNECTICUT MEDICINE with the informative articles about various aspects of Lyme disease. I congratulate you for this collection of papers that will educate, not only the general public, but also the practicing physicians in your state. I only wish copies could be made available to every hospital and physician's office throughout this country.

Much has been written about the history of Lyme disease, and many erroneous statements have been made in regard to the circumstances that led to the discovery of the causative agent. Joel Lang has done an outstanding job documenting facts rather than "fantasia fantastica" guided by political interests.

Also many thanks for the excellent brochure "Fight the Bite" and the new edition of Pfizer's "Lyme Disease." Both pamphlets will contribute greatly to our efforts to educate the public about this disease.

With best wishes and regards.

Willy Burgdorfer, Ph.D., M.D.

Department of Health and Human Services
National Institutes of Health
Rocky Mountain Laboratories
Hamilton, Montana 59840

PERSONNEL SHORTAGES IN STATE HOSPITALS

To the Editor: The first psychiatric hospital in Connecticut was built because of the interest and activities of the Connecticut State Medical Society that established a committee under the chairmanship of Eli Todd to investigate the care and treatment of the mentally ill in our state. I would hope that this interest and concern continues in 1989 as well. The budgetary deficiencies have led to a crises in which state personnel are being encouraged to retire, and new hirings are done on a ratio of 4:1. The resulting shortage of health care workers has in turn led to increased pressure to discharge patients from the state hospitals. This means that patients are being discharged not on the basis of their having recovered sufficiently to manage outside of the hospital but rather that there isn't the personnel to care for them. I appeal to the physicians of the state, and the Medical Society to intervene to ensure that patients are as adequately cared for now as they were over a hundred years ago.

Leo H. Berman, M.D.

Westport

WHY A MANDATED STUDY?

To the Editor: With so many state medical societies as well as the AMA to monitor professional needs and trends, it seems an embarrassment that we needed a congressionally mandated study (RBRVS) to investigate a compensation mechanism for physicians that was commensurate with their basic medical skills.¹

For a long time family physicians and general internists have endured a lower level of compensation relative to other specialties, and both have been aware for a long time of their paradoxically descendant role at a time when society needs personal physicians more than ever: but neither local medical societies or the AMA have ever acknowledged the role of these generalists with the recognition, professional or financial, accorded to other specialties.

Our medical governing bodies need a more informed and enthusiastic body politic if they are to serve all members of our profession well in the future.

Edward J. Volpintesta, M.D.

Bethel

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IN MEMORIAM

ADZIMA, JOSEPH M., University of Maryland, 1927. Dr. Adzima was a surgeon in the Fairfield County area since 1927. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 28 July 1989 at the age of 85.

ANDERSON, FRED A., Boston University, 1940. Dr. Anderson was a surgeon in the New London County areas since 1950. He was a member of the New London County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 6 August 1989 at the age of 74.

BATTISTA, ANTHONY W., Tufts, 1924. Dr. Battista was an internist in the New Haven County area since 1924. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society; died 27 April 1989 at the age of 90.

BRAND, ELLIOTT S., New York University, 1943. Dr. Brand was a urologist in the New Haven County area since 1947. He was a member of the New Haven County Medical Association and the Connecticut State Medical Society; died 6 May 1989 at the age of 72.

CAPODILUPO, VINCENT M., University of Naples, 1954. Dr. Capodilupo was an internist in the Fairfield County area since 1961. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 6 June 1989 at the age of 65.

CAPPUCCI, LOUIS W., Georgetown, 1953. Dr. Cappucci was an internist in the New Haven County area since 1955. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 10 May 1989 at the age of 63.

EARLE, LYON H., JR., Tufts, 1950. Dr. Earle was a medical director in the Hartford County area since 1951. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 25 April 1989 at the age of 68.

FOLEY S, FRANCIS X., Boston University, 1934. Dr. Foley was an orthopedic surgeon in the Fairfield County area since 1936. He was a member of the Fairfield County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 7 July 1989 at the age of 80.

GALINSKY, DAVID, Tufts, 1936. Dr. Galinsky was an internist in the Hartford County area since 1937. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 20 April 1989 at the age of 78.

GALLO, FRANCIS P., Jefferson Medical School, 1934. Dr. Gallo was a general practitioner in the Litchfield County area since 1935. He was a member of the Litchfield County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 28 June 1989 at the age of 78.

LABELLA, LOUIS O., Columbia Physicians & Surgeons, 1925. Dr. LaBella was a general surgeon in the Middlesex County area since 1926. He was a member of the Middlesex County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 2 August 1989 at the age of 91.

LENEHAN, J. RICHARD, Jefferson Medical School, 1937. Dr. Lenehan was an internist in the Hartford County area since 1941. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 25 July 1989 at the age of 77.

MOLUMPHY, PAUL E., Yale Medical School, 1944. Dr. Molumphy was an obstetrician and gynecologist in the New Haven County area since 1951. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 1 August 1989 at the age of 69.

NELSON, WALTER N., George Washington University, 1926. Dr. Nelson was an orthopedic surgeon in the Middlesex County area since 1926. He was a member of the Middlesex County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 4 April 1989 at the age of 89.

PELLICCIA, ORLANDO, Johns Hopkins, 1939. Dr. Pelliccia was a general surgeon in the New Haven County area since 1941. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 3 July 1989 at the age of 76.

PURNEY, JOHN, McGill Medical School, 1939. Dr. Purney was an obstetrician and gynecologist in the Hartford County area since 1940. He was a member of the Hartford County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 3 May 1989 at the age of 78.

PURNELL, OLIVER J., Cornell University, 1942. Dr. Purnell was a surgeon in the Tolland County area since 1943. He was a member of the Tolland County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 10 August 1989 at the age of 71.

ROTHSTEIN, DAVID, Long Island College Hospital, 1925. Dr. Rothstein was a general practitioner in the New Haven County area since 1974. He was a member of the New Haven County Medical Association, the Connecticut State Medical Society, and the American Medical Association; died 28 April 1989 at the age of 88.

TUTLES, ALEXANDER J., Tufts, 1930. Dr. Tutles was a gerontologist in the Hartford County area since 1930. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died 25 July 1989 at the age of 86.

WILLIAMS, WILLIAM E., Columbia, 1947. Dr. Williams was a general practitioner in the Hartford County area since 1948. He was a member of the Hartford County Medical Association and the Connecticut State Medical Society; died 13 June 1989 at the age of 66.

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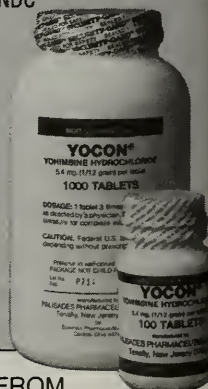
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1. A. Morales et al., New England Journal of Medicine: 1221. November 12, 1981.
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Prognostic Factors in Primary Breast Cancer

MICHAEL REISS, M.D.

ABSTRACT—Approximately 25% of women with node-negative breast cancer treated with surgery alone eventually experience a relapse of their disease. Survival in this group of patients correlates with the level of estrogen-receptors and inversely with the size of the primary tumor. Moreover, the rate of tumor growth, as determined either clinically or by using *in vitro* techniques, such as thymidine-labeling and flow cytometric measurements of DNA content, can be used to identify patients with node-negative breast cancer who have a high probability of recurrence. Based on such an analysis, the subset of patients with slow growing cancers may be spared adjuvant cytotoxic therapy. On the other hand, a rapid tumor growth rate predicts for a higher than usual chance of relapse among patients with node-positive breast cancer. Therefore, this subset of women may benefit from more prolonged and/or intensive adjuvant chemotherapy than is currently recommended. Finally, ongoing studies of structural or functional disturbances of proto-oncogenes in breast cancer can be expected to provide practitioners with additional prognostic indicators that will lead to further improvements in the management of this group of diseases in the near future.

Introduction

THE principal treatment of primary breast cancer consists of either radical surgery or limited surgery in combination with radiation therapy. In recent years, the inclusion of systemic medical therapy (hormonal or cytotoxic chemotherapy) in the primary treatment plan has been advocated for patients who are at high risk for the development of recurrent disease. In order to identify the subsets of patients whose prognosis will or will not improve by the addition of systemic therapy, those characteristics of the primary tumor that confer prognostic information need to be identified.

Whether or not medical therapy has a significant impact on survival of patients with breast cancer can only be determined by comparison with the effectiveness of loco-regional treatment alone. Table 1 summarizes the natural history of breast cancer in patients treated with radical surgery only. In addition, four large-scale ran-

domized studies, conducted both in the United States and in Europe, have demonstrated that limited surgery in combination with primary radiation therapy is as effective as radical surgery in controlling stage I and II breast cancers.¹⁻⁴ Therefore, approximately 50% of all patients with operable breast cancer are cured by surgery and/or radiation therapy as the principal forms of treatment.

In approximately 50% to 60% of patients with primary breast cancer, the disease does not involve axillary lymph nodes at presentation (node-negative breast cancer). Of these patients, approximately 75% are cured with surgery alone (see Table 1). Recently, early results have been published of a number of large-scale studies in which patients with node-negative breast cancer were randomly assigned to receive adjuvant chemo- or hormonal therapy.⁵⁻⁷ A small but statistically significant improvement in relapse-free survival in favor of the treated groups was noted in each of these studies. Based on these observations, the National Cancer Institute has issued the recommendation that all patients with node-negative breast cancer be considered for adjuvant systemic therapy. However, given the fact that only 25% of these patients are expected to recur after surgery, it is critical to identify prognostic factors other than the present of axillary metastases that will allow us to recognize the subset of patients who are at high risk for recurrence and spare the majority of these patients unnecessary systemic therapy.

Of patients who present with disease that demonstrates metastatic spread to axillary lymph nodes, approximately 60% will relapse and eventually succumb to the disease. A large number of randomized studies have demonstrated the efficacy of adjuvant chemotherapy in reducing the rate of tumor recurrence in patients whose tumors have metastasized to between one and three axillary lymph nodes. By and large, the chemotherapy regimens that are currently in use have reduced the recurrence rate from 50% to approximately 35% in this group of patients. It is evident that the group of women with node-positive breast cancer includes some who probably do not require systemic therapy at all, as well as others who will relapse in spite of adjuvant chemotherapy. It is pertinent, therefore, to identify the prognostic factors that will allow us to discriminate between patients

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with node-positive breast cancer who might benefit from more intensive systemic therapy and those who do not require any adjuvant treatment at all.

Table 1
Long-term Survival of Patients with Breast Cancer Treated with Surgery

No. Patients	Follow-Up (years)	Stage	% Cured	Reference
1458	30	All	43	[14]
704	22	I and II	30	[41]
14731	5-18	I	54	[42]
		II	27	
		III	19	
1036	10	I	77	[43]
		II	49	
304	10	I	91	[44]
		II	57	
		III	34	

Prognostic Factors

I. Regional lymph node metastases

The presence of metastases in axillary lymph nodes has been universally accepted as the strongest predictor of survival of patients with breast cancer for many years. In an analysis of more than 20,000 cases of patients with breast cancer treated with surgery alone, Wilson et al⁸ found a linear relationship between the number of involved axillary nodes and patient survival at five years. Recently, Carter et al⁹ reviewed the outcome of approximately 25,000 cases of women with breast cancer recorded in the Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute. This study confirmed the observation that the presence of axillary lymph node metastases is a strong predictor of survival, independent of the size of the primary tumor. Furthermore, a number of investigators have reported that patients who have tumors with four or more positive axillary nodes have a significantly greater likelihood of recurrence than those with one to three involved lymph nodes.⁹⁻¹² It is important to realize that the two largest trials of adjuvant chemotherapy with a follow-up of greater than 10 years have demonstrated an improvement on patient survival only for premenopausal women who had tumors with one to three axillary nodes.¹³ Studies of more intensive adjuvant chemotherapy for patients who are at higher risk for recurrence are currently in progress.

II. Size of the primary tumor

The size of the primary tumor has been recognized as one of the main prognostic indicators in primary breast cancer for many years. In 1977 Robbins and Berg¹⁴ reported the outcome of 1,458 patients treated at Memorial Hospital in New York with surgery only. This series is particularly important because the median follow-up exceeded 30 years. Within the subset of patients with node-negative tumors, long-term survival decreased with increasing size of the primary tumor up to 4.9 cm.

Interestingly, patients with lesions > 5 cm did as well as those with tumors of 3-3.9 cm. This observation suggests that tumors that remain confined to the breast for a long time represent a biologically distinct subgroup with a relatively good prognosis. In this series, the presence of axillary nodal metastases conferred an additional negative prognostic effect within each size-grouping.¹⁴ Among the 25,000 patients with breast cancer recorded in the SEER Program of the National Cancer Institute, survival rates at five years ranged from 45.5% for patients with tumors $\geq$ 5 cm and $\geq$ 4 involved axillary lymph nodes to 99.2% for patients with tumors < 0.5 cm without axillary node involvement.⁹ Two findings of this study are of particular interest. First, in the absence of nodal metastases, the survival of patients with primary lesions smaller than 1 cm is > 98%. This observation was confirmed by Rosen et al¹⁵ who estimated the cure-rate of patients with node-negative tumors < 1 cm to be 89%, compared to 77% for patients with node-negative tumors between 1 and 2 cm in diameter. Consequently, it is unlikely that adjuvant systemic therapy would be able to improve the outcome of these patients significantly. Secondly, Carter et al⁹ also identified a subset of patients with primary tumors < 1 cm and $\geq$ 4 positive axillary nodes whose overall survival was shorter than expected on the basis of tumor size alone. Therefore, this observation suggests the existence of a subset of aggressive tumors that metastasize relatively early in their course. It is important to recognize this subset of patients, because they may benefit from intensive adjuvant chemotherapy.

Table 2
Relapse-free Survival as a Function of ER Status in Patients with Node-negative Breast Cancer

No. Patients	Follow-Up (years)	ER +	ER -	P-Value	Reference
94	5	83	73	< 0.05	[45]
556	6	83	86	NS	[46]
510	5	78	67	< 0.034	[47]
464	4	79	63	< 0.001	[18]

NS: Not statistically significant

III. Pathology

The vast majority (70% to 80%) of malignant tumors of the breast are classified histologically as invasive (or infiltrating) ductal carcinomas.¹⁶ A number of pathological features have been identified that carry prognostic significance. Histological grading refers to the degree of differentiation and the mitotic activity of the tumor. The extent of tubule formation, nuclear hyperchromasia, and mitotic figures per microscopic field are the parameters used to classify a tumor into grade I (well-differentiated), grade III (poorly-differentiated), or grade II (intermediate) groups. A number of studies have demonstrated a strong correlation between histological grade and the presence of axillary lymph node metastases. In multivariate analyses of prognostic factors in the subset of patients with tumors involving lymph nodes (stage II), histological grade grouping does not provide significant addi-

tional prognostic significance. However, within the subset of patients with node-negative tumors, histological grading may be helpful to identify those at high risk for recurrence who might benefit from adjuvant chemotherapy. Fisher¹¹ analyzed the outcome of 279 patients with node-negative tumors. In this study, histological grade III was a significant predictor of recurrence at 10 years.¹¹ Similarly, Rosen et al¹⁷ studied 644 patients with node-negative carcinomas who had been followed at Memorial Hospital for a median duration of 18 years. The prognosis was especially favorable in cases with a tumor size ≤ 1 cm, tubular, medullary, papillary, colloid types of carcinoma, or grade I invasive ductal carcinomas. In contrast, unfavorable characteristics included larger tumor size, the presence of lymphatic tumor emboli, blood vessel invasion, peritumoral lymphoplasmacytic reaction, and histological grade III.¹⁷

IV. Estrogen and progesterone receptors (ER, PgR)

The proliferation of normal mammary epithelium appears to be controlled by estrogen and progesterone hormones. It is thought that, during early stages of breast carcinogenesis, tumor cell growth remains, in part, under hormonal control. During the past 15 years, a number of studies have addressed the relationship between the presence of steroid receptors in tumor tissue and the clinical course of patients with breast cancer. Table 2 shows that four of five studies of patients with node-negative tumors have demonstrated that patients whose tumors contained ERs have a significantly lower risk for relapse than those whose tumors lacked steroid receptors. Furthermore, in a study of 1,647 patients whose tumors did not involve axillary lymph nodes, McGuire et al¹⁸ showed by multivariate analysis that the size of the primary tumor and the absence of ERs were the two most important independent prognostic indicators of relapse. These same investigators have also analyzed the prognostic factors that determined the outcome of 1,529 patients with node-positive tumors.^{18,19} The number of involved nodes, PgR status, and tumor size were the strongest independent predictors of both relapse-free and overall survival. Furthermore, although the presence of ER in the tumor increased the likelihood of overall survival, multivariate analysis revealed that the level of PgR was more important than the level of ER for predicting the chance of recurrence. This observation has since been validated in a prospective study conducted at Case-Western Reserve University in Cleveland.²⁰ At a median follow-up of 69 months, this study confirmed the observation that the number of positive lymph nodes and the PgR content of the tumor were the two significant predictors of disease-free and overall survival in patients with node-positive breast cancer.¹⁸

V. Proliferative activity

Although tumor size, the propensity to metastasize to regional lymph nodes, and the presence of steroid hor-

mone receptors have been identified as important prognostic features of breast cancer, none of these parameters take into account the cancer's rate of growth. A number of different methods have been developed to provide an estimate of the tumor growth rate and have been shown to be of value in assessing the prognosis of patients with breast cancer.

Table 3
Clinical Index of Tumor Growth Rate as Proposed by Charlson and Feinstein²¹

Auxometric Group	Progression Interval	Transition Events
Slow	≥ 4 months	Absent
Intermediate	< 4 months	Absent
Rapid	Any	Present

A. CLINICAL INDEX OF GROWTH RATE

In 1980, Charlson and Feinstein²¹ reported on a simple clinical method to estimate the kinetics of breast cancer growth. Two features of the patients' history were used to classify tumors as slow, intermediate, and fast growing (see Table 3): 1. the duration of the *progression interval*, ie, the time elapsed between the first noted manifestation of breast cancer and the beginning of treatment; and 2. the occurrence of *transition events*, ie, additional signs or symptoms that were noted between detection and treatment: *local*: ulceration, growth, asymmetry, edema, change of consistency of the mass; *regional*: enlargement of nodes, skin nodules; *systemic*: weight loss $> 10\%$ of body weight, symptoms from metastases. In the original report, the predictive value of this clinical index was tested among a group of 685 women who received their primary treatment for breast cancer at Yale-New Haven Hospital between 1962-69.²¹ Within the group of patients whose tumors did not involve axillary lymph nodes, 75% to 80% of patients with tumors that grew at a slow or intermediate rate were alive at 10 years, compared to only 60% of those with fast growing cancers. Of patients with node-positive tumors, 60% of those with slow growing lesions were alive at 10 years, compared to 25% to 35% of those with faster growing tumors.²¹ The prognostic significance of the clinical growth rate was independent of tumor size and the degree of axillary node involvement. These conclusions were subsequently confirmed in a retrospective analysis of a second cohort of 465 patients.²² This classification of primary breast cancers by rate of growth was validated by Boyd et al²³ in a prospective study conducted at the Princess Margaret Hospital in Toronto. These investigators interviewed 756 patients with operable breast cancer who participated in a trial of adjuvant therapy between 1965 and 1972. As is shown in Table 4A, the rate of tumor growth correlated well with overall long-term survival. Moreover, the growth kinetics of the tumor were independent of anatomic stage, nodal status, and histological grade.²³ Within each nodal group, patients with slow growing tumors had a significantly better survival than those with intermediate and faster grow-

Table 4
Prospective Study of Clinical Index of Growth Rate²³

A. Survival			
<i>Auxometric Group</i>	<i>No. Patients</i>	<i>Overall Survival at 10 Years (%)</i>	
Slow	93	70	
Intermediate	488	55	
Rapid	168	45	

B. Relative Death Rates			
<i>Auxometric Group</i>	<i>None</i>	<i>Nodal Metastases</i>	
		<i>1 - 3</i>	<i>4</i>
Slow	0.20	0.58	0.99
Intermediate	0.61	0.84	1.97
Rapid	0.62	1.23	1.87

ing ones (see Table 4B). A similar correlation between tumor growth rate and survival was noted in the University of Louisville Breast Cancer Detection and Demonstration Project.²⁴ The long-term survival of women whose breast cancers had been detected in between yearly screening mammographies (ie, fast growing) was 74 ± 9%, compared to 94 ± 4% for those whose tumors had been found by mammography (ie, slower growing).

B. [³H] THYMIDINE LABELING:

Prior to cell division, a cell has to undergo a period of DNA synthesis during which it doubles its DNA content. Radiolabeled thymidine is incorporated into DNA during this premitotic phase of DNA synthesis (S-phase). The fraction of a cell population that incorporates the radiolabel is proportional to the number of cells that are synthesizing DNA and traversing the cell cycle. This parameter is referred to as the thymidine labeling index (TLI).²⁵ Alternatively, staining of cells with fluorescent dyes that bind to DNA allows cellular DNA content to be measured by flow-cytometric analysis. Such an analysis also provides an estimate of the fraction of cells that are going through the S-phase of the cell-cycle (% S-phase). Although the proportion of cells undergoing DNA synthesis can be calculated using either one of these two techniques, thymidine labeling requires fresh tissue and is tedious and time-consuming, whereas flow-cytometric analysis can be performed on frozen tissue and is technically simpler and rapid. The prognostic value of either the TLI or the percentage of cells in S-phase has been determined in a number of studies. Tubiana et al²⁶ determined the TLI of breast biopsies of 128 patients seen at the Institut Gustave-Roussy. Of these, 96 underwent a modified radical mastectomy. The remaining 32 patients presented with locally advanced breast cancer and were treated with radiation therapy alone or in combination with surgery. Therefore, no information is available on nodal involvement in this group. None of the patients received chemotherapy. At 10 years posttreatment, 25% of patients with a low TLI

had relapsed, compared to 53% and 62% of those who had had tumors with an intermediate or high TLI, respectively. At the National Cancer Institute of Italy, Silvestrini et al^{27,28} determined the TLI on tumors of 215 node-negative patients who were treated with surgery alone. The TLI was independent of the size of the primary tumor and ER status. At a median follow-up of seven years, both the relapse-free survival and overall survival of patients with tumors with a low TLI was significantly greater than of women with tumors with high TLI (see Table 5). Interestingly, multivariate analysis revealed that, within this group of patients with node-negative cancers, the prognostic significance of the TLI was stronger than either tumor size or ER status. These same investigators have recently reported the results of a more extensive study, encompassing a larger group of 971 patients.²⁸ Among the subset of patients with ≤ 3 involved axillary nodes, who had received adjuvant chemotherapy following their primary surgery, no difference in relapse-rates were noted between those with a low compared to a high TLI. However, among patients with > 3 nodal metastases, a high TLI was a significant predictor of relapse, irrespective of whether or not the patients had received adjuvant chemotherapy (see Table 5). The authors postulate that the adjuvant chemotherapy had effectively canceled out the negative prognostic effect of a high TLI among women with one to three nodal metastases, but not for patients with a greater number of involved nodes, whose survival is not affected by chemotherapy regimens tested thus far.²⁸ In this country, Meyer²⁹ has analyzed the TLI of 268 node-negative tumors. At a median follow-up of five years, only 11% of patients whose tumors had a low TLI had relapsed, compared to 35% of those with tumors with a high TLI. Among patients with node-positive tumors, 48% of those with a high TLI recurred, compared with 27% and 21% of those with intermediate and low TLI, respectively. As a predictor of recurrence, TLI was independent of ER and nodal status. Furthermore, percentage of S-phase cells, as determined by flow cytometry on the same tumor specimens, correlated well with the TLI.²⁹ Finally, Clark et al³⁰ analyzed 400 samples of primary, node-negative breast tumors by flow cytometry. Of these, 112 were diploid. Within this subgroup, those with a high percentage of S-phase cells had a significantly worse relapse-free as well as overall survival than those with a low percentage of S-phase. In accord with the earlier studies of TLI, the percentage of cells in S-phase was a stronger predictor of recurrence than either tumor size or ER status among these patients with node-negative breast cancer.

C. EGF/TGFα-RECEPTORS

Type alpha transforming growth factor (TGFα) has been identified as a polypeptide growth factor for breast epithelial cells. TGFα induces cell proliferation by binding to and activating the receptor for epidermal growth factor (EGF-receptor). Moreover, estrogens induce the

secretion of TGF α by ER-positive breast cancer cells, whereas the growth factor is constitutively produced by ER-negative cancer cells. These observations have led to the hypothesis that the density of cell surface receptors for TGF α reflects the proliferative activity of the tumor and represents yet another prognostic indicator in breast cancer.

Table 5
A. Five-year Relapse-free Survival (%) of Patients with Breast Cancer as a Function of TLI and Stage²⁸

Involved Nodes	No. Patients	Low TLI	High TLI	P-Value
0	414	83	60	0.0001
1 - 3	306	78	61	0.017
≥ 4	251	52	37	0.02

B. Five-year Overall Survival (%) of Patients with Breast Cancer as a Function of TLI and Stage²⁸

Involved Nodes	No. Patients	Low TLI	High TLI	P-Value
0	414	96	86	0.0001
1 - 3	306	87	82	NS
≥ 4	251	81	60	0.0013

NS: Not statistically significant; TLI: Thymidine Labeling Index

In two small studies, an inverse correlation was found between the expression of ERs and PgRs on the one hand, and EGF-receptors on the other.^{31,32} In these studies, 70% to 90% of the specimens were either ER-negative, EGF-receptor positive, or ER-positive, EGF-receptor-negative. In addition, the majority of the ER-positive, EGF-receptor-negative tumors had a low labeling index, whereas the majority of the ER-negative, EGF-receptor-positive tumors had a high TLI.³² Tumors that expressed EGF-receptors had a) a significantly higher histological grade; b) were significantly more frequently associated with nodal involvement; c) had a size of 2.1-3.5 cm. However, no correlation was found between the absence of EGF-receptors and any of these three parameters.³³ Interestingly, in a small study of 26 node-negative patients, none of those with EGF-receptor-negative tumors recurred, whereas 65% of those with EGF-receptor-positive tumors relapsed within three years.³⁴ In summary, these preliminary data suggest that the expression of EGF-receptors by breast cancer cells might be indicative of a more rapid growth rate. However, it is not clear whether this information provides prognostic information above and beyond that obtained by TLI or flow-cytometry.

VI. Genetic changes

A. ONCOGENES

During the past decade it has become evident that the proto-oncogenes, that are involved in the regulation of cellular growth and differentiation, are often mutated or inappropriately expressed in cancer. Therefore, numerous investigators are attempting to link specific genetic changes to individual cancers or to prognostic subsets

within a particular group of cancers (see³⁵ for review).

The amplification or overexpression of the HER-2/*neu* proto-oncogene is found relatively frequently in breast tumors. Slamon et al³⁶ examined 526 primary breast cancers, 146 of which (28%) showed evidence of HER-2/*neu* amplification. This feature did not correlate with ER- or PgR-status, tumor size, or age of the patient, but did correlate with the presence of > 3 axillary nodal metastases. Within the subgroup of 181 node-negative patients, HER-2/*neu* amplification was not associated with disease outcome. However, among the 345 patients with node-positive tumors, the number of involved lymph nodes and amplification of the HER-2/*neu* oncogene were the two strongest predictors of shortened time to relapse as well as overall survival at five years.³⁶ Zhou et al³⁷ analyzed 86 primary and 12 nodal metastases of breast cancers, and detected HER-2/*neu* amplification in 18/98 (18%). Amplification of the HER-2/*neu* gene was significantly more frequent in stage III and IV tumors than in stage I and II tumors. Berger et al³⁸ found HER-2/*neu* amplification in 13/51 (25%) primary breast tumors, which correlated with the degree of nodal involvement. In summary, amplification of the HER-2/*neu* proto-oncogene is found in approximately one fourth of all primary breast carcinomas and correlates with the extent of nodal involvement. In contrast to the three studies described above, van de Vijver et al³⁹ found that overexpression of the HER-2/*neu* proto-oncogene in 27/189 (14%) primary breast tumors correlated only with tumor size, but not with nodal status, age, histological type, histological grade, or patient survival. Thus, although the HER-2/*neu* proto-oncogene is apparently often expressed in breast carcinoma, the biological significance of this finding remains unclear and controversial.

B. CHROMOSOMAL CHANGES: ANEUPLOIDY

In general, progression of malignant tumors is associated with the acquisition of chromosomal abnormalities. Gross changes in the number of chromosomes per cell (ie, aneuploidy) can be detected by flow cytometry. To date, most of the studies of aneuploidy as a prognostic indicator in breast cancer have included patients with all stages of the disease (see Table 6). In spite of significant variations in the numbers of patients studied and the duration of follow-up, four of these studies have led to the conclusion that aneuploid tumors are associated with a significantly shorter time to relapse and a decreased survival (see Table 6). Two of these studies have only included patients with node-negative breast cancers.^{30,40} In one of these, Clark et al³⁰ found aneuploidy to be the most important predictor of relapse in this group of women. Among a small group of 29 women with node-negative tumors who had been followed for at least 10 years, Frey et al⁴⁰ found that only 8/18 (42%) of those with aneuploid tumors were alive at 10 years, whereas none of the patients with diploid tumors died of breast cancer. Although these studies require confirmation,

they suggest that aneuploidy may represent yet another characteristic of breast cancer that will allow us to identify those patients who are at a relatively high risk for recurrence of their disease.

Discussion

Of all the women who present with node-negative breast cancer, approximately 25% eventually succumb to recurrent disease. Based on randomized trials in which patients were stratified according to size of their primary tumors and the level of ER, adjuvant chemotherapy or hormonal therapy is currently advocated for all women in this group. Methods to identify only the small subgroup of patients who can be expected truly to benefit from systemic treatment are urgently needed, in order to spare the majority of these patients unnecessary and potentially toxic therapy. Node-negative breast cancers with any of the following features appear to have an extremely favorable prognosis: size of primary tumor < 1 cm; high levels of ER; grade I infiltrating ductal and well-differentiated tumors; slow growth rate (measured using either a clinical index, TLI or flow-cytometric analysis); and a normal (diploid) number of chromosomes. In contrast, unfavorable signs include: large tumor size; high histological grade; absence of ER and PgR; rapid growth rate; and aneuploidy. In future studies of adjuvant chemotherapy for women with node-negative breast cancer, patients will be stratified according to all of these prognostic factors in order to determine whether or not these factors effectively discriminate between the subsets of patients who will or will not benefit from systemic therapy. Large numbers of patients will have to be accrued to these studies and followed for prolonged periods of time before any definitive conclusions can be drawn. However, the aim of sparing approximately 30,000 women per year unnecessary systemic therapy more than warrants the effort.

Of all patients who present with operable breast cancer involving axillary lymph nodes, approximately 60% will relapse after loco-regional treatment alone. Thus far, the addition of adjuvant chemotherapy has led to an improvement in survival of approximately 15% to 20% for premenopausal women with node-positive breast cancer. Consequently, we must learn to recognize those women who do not require adjuvant systemic therapy because they are cured with local treatment only, and, on the other hand, those who might benefit from more intensive adjuvant therapy because they are destined to relapse in spite of the currently available types of medical treatment.

The evidence presented above suggests that features of the primary tumors that predict for an unusually high rate of relapse in patients with nodal involvement include the presence of greater than three axillary lymph node metastases; absence of PgR; rapid growth rate (as measured by clinical index, TLI, or percentage of cells in S-phase); and aneuploidy. No good discriminants have yet been identified that indicate which patients with node-positive cancers might not require adjuvant chemotherapy.

Finally, alterations in the structure or expression of

Table 6 Diploidy versus Aneuploidy in Primary Breast Cancer				
No. Patients	Follow-Up (years)	Relapse-Free Survival (%)	Overall Survival (%)	Reference
638	1.5	89 vs. 79	NA	[48]
59	4 - 5	70 vs. 59	NA	[49]
74	3	NA	100 vs. 37	[50]
308	8	NA	74 vs. 51	[51]
565	3 - 5	78 vs. 67	80 vs. 69	[52]
345	5	88 vs. 74	NS	[30]
29	10	NA	100 vs. 42	[40]

NA: Not available; NS: Not statistically significant.

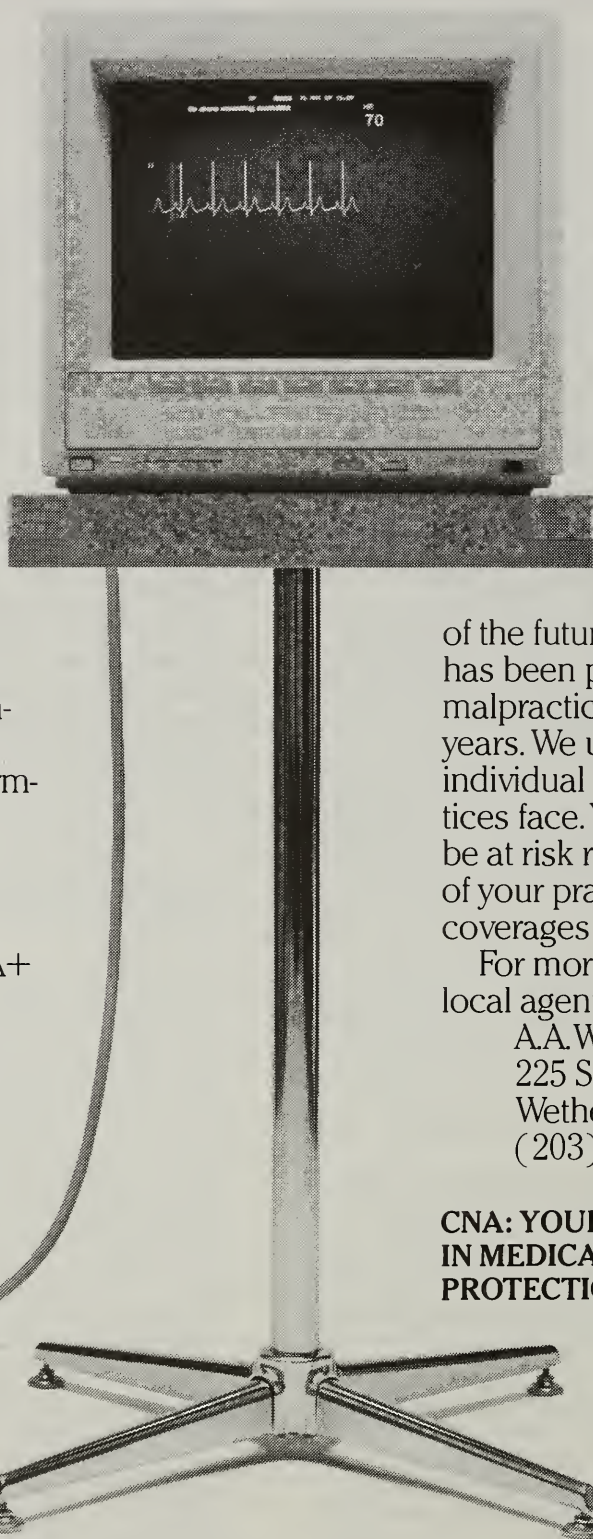
proto-oncogenes represent new biological markers of cancer. The HER-2/*neu* proto-oncogene is especially frequently overexpressed in node-positive breast cancers and represents a new prognostic factor. The biological role of this oncogene in breast cancer remains to be elucidated.

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Continent Reservoirs

JOHN W. COLBERG, M.D., STEPHEN F. SCHIFF, M.D.,
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ABSTRACT—Continent urinary diversion is a major advance in the treatment of selected patients following cystectomy. Twenty-eight patients have undergone some form of continent urinary diversion at Yale New Haven Hospital during the past three years; thirteen have a continent reservoir with a continent stoma on the abdominal wall, and empty the urine by self-intermittent catheterization, and 15 have a reservoir anastomosed to the urethra, the majority of whom void spontaneously. All are continent by day and over 50% are continent at night. A recent modification in the construction of the urinary reservoir would appear to have resolved the problem of nocturnal incontinence. The results and urodynamic studies in this group of patients are discussed, and it is concluded that a detubularized intestinal reservoir provides a safe and effective method for continent urinary diversion in selected patients following cystectomy.

CONSTRUCTING the ideal substitute for a functioning urinary bladder has been a long-standing problem. It has been a fertile field for the creative talents of urologic surgeons during the past century. In 1852 John Simon of St. Thomas' Hospital in London treated a young boy with exstrophy of the bladder by placing a necrosing suture through the lower ureter and rectum to create a urorectal fistula.¹ The boy had urinary control, by using his anal sphincter, for 11 months until he developed a stricture and stones at the site of the fistula and succumbed to uremia and urinary sepsis. From this early experience, the technique of ureterosigmoidostomy was later developed and was the urinary diversion of choice until the 1950s. While ureterosigmoidostomy provided for urinary continence, it did so at the risk of recurrent infections that frequently led to deterioration of renal function and electrolyte disturbances. Methods were devised for implanting the ureters into the bowel so as to prevent the reflux of fecal material into the kidneys.²

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While this reduced the incidence of pyelonephritis, it persisted as a serious problem in about half the patients.³ Furthermore, there is now growing evidence that there is an increased risk of colonic neoplasms developing in patients with long-term diversion of urine into the intact large bowel.⁴

Subsequently procedures were developed to separate the urinary tract from the fecal stream. Boyer and Gersuny implanted the ureters into the isolated rectum and advanced the transected distal sigmoid through the anal sphincter alongside the rectum to provide continence of both urine and feces.⁵ These procedures proved to be only partially successful.

Sieffert in 1935 in Germany devised a jejunal urinary conduit,⁶ which did not become popular probably because of the lack of a suitable adhesive appliance to collect the urine from the abdominal stoma. Gilchrist and Merrick constructed a continent pouch of isolated cecum and right colon and brought the terminal ileum out onto the skin. They claimed that the ileocecal valve was effective, in their cases, in maintaining continence, and allowed the patients to empty the pouch at regular intervals by self-catheterization.⁷ This was the first attempt at a continent diversion with an abdominal stoma. At about the same time, Bricker devised the ileal conduit, in which an isolated 10 cm segment of ileum was used to join the retroperitoneally situated ureters to the skin, and provided for a large common stoma over which an appliance could be fitted to collect the urine.⁸ This became the standard method of urinary diversion for the next 30 years. Couvelaire in France⁹ and Gil Vernet in Spain¹⁰ continued to experiment with continent forms of diversion. They anastomosed isolated loops of ileum and sigmoid directly to the urethra following cystectomy. Camey persisted with this technique and published his 25-year experience in 1977.¹¹ While these procedures provided for an internal reservoir, they were restricted to male patients, and the majority were incontinent at night.

In 1977 Kock and his associates described a continent urinary reservoir with an abdominal stoma from ileum that was modeled after the fecal reservoir that is used in

patients following total colectomy for inflammatory bowel disease.¹²

Several techniques have been described since in which the reservoir is constructed in a variety of ways from detubularized segments of right colon and cecum together with adjacent portions of ileum. The distal ileum is used, in most instances, for the continent abdominal stoma, the ileocecal valve being reinforced either by intussusception of the ileum through the valve or by plication of the terminal ileum.^{13,14,15} These reservoirs have also been used as neobladders by anastomosing them directly to the transected membranous urethra in selected male patients. We have found that the most successful bladder substitute is constructed from detubularized ileum with the ureters being implanted by an antireflux method directly into the pouch.¹⁶

The renewed interest in continent urinary diversions has occurred because of the disappointing long-term results of ileal conduit diversions; a demand, especially by younger patients, for a diversion without the need for an external appliance; the development of self-intermittent catheterization; and an improvement in surgical techniques. Furthermore the abandonment of preoperative radiation in the treatment of bladder cancer has made continent diversion a feasible alternative in these patients. The usual indication for a continent urinary diversion has been following radical cystectomy for carcinoma of the bladder. It does, however, have application in patients with neurogenic bladder dysfunction and in refractory cases of interstitial cystitis. Twenty-seven continent urinary diversions have been performed at the Yale-New Haven Medical Center during the past three years, and one was performed in 1963. This paper describes the results in this select group of patients.

Materials and Methods

Twenty-eight patients have had a continent diversion of whom 15 had bladder substitutions and 13 had continent reservoirs constructed.

The 15 patients that underwent bladder replacement, in which the intestinal pouch was anastomosed to the membranous urethra, were all males age 14 to 68 years. Thirteen patients had a radical cystoprostatectomy for malignant disease, one had a cystectomy for severe refractory interstitial cystitis, and another suffered accidental loss of his bladder in infancy during herniorrhaphy. The first patient had a neobladder constructed from a nondetubularized segment of a sigmoid colon in 1963, following cystectomy for cancer. The ureters were implanted into submucosal tunnels in the tinea. This patient developed bilateral hydroureteronephrosis five years later which required revision. He ultimately died 19 years after his original procedure from a myocardial infarction. No more diversions of this type were performed because preoperative radiation therapy prior to

cystectomy became the treatment of choice for bladder cancer at that time. Three bladder substitutes were constructed from detubularized segments of cecum and right colon. The ureters in two of these cases were implanted into the terminal ileum which had been intussuscepted through the ileocecal valve to prevent reflux. In the other cases, the ureters were implanted into submucosal tunnels in the right colon. Four were constructed by placing 12-14 cm of ileum as a patch onto the detubularized cecum and right colon. The ureters in these cases were implanted into the terminal ileum in one, submucosally into the colon in an another, and into an intussuscepted portion of ileum proximal to the ileal patch in two. One bladder was created from a 28 cm loop of ileum detubularized and folded in two, augmented with the detubularized existing sigmoid conduit. The last six patients had neobladders constructed from a 60 cm portion of detubularized ileum with the ureters being implanted into the pouch by the LeDuc method shown in Figure 1.

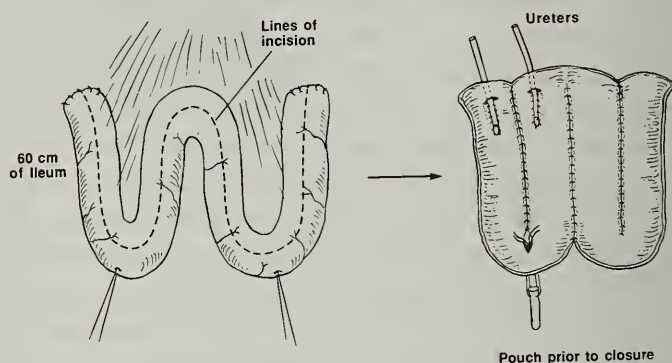


Figure 1
Ileal pouch used as bladder substitute and anastomosed to membranous urethra.

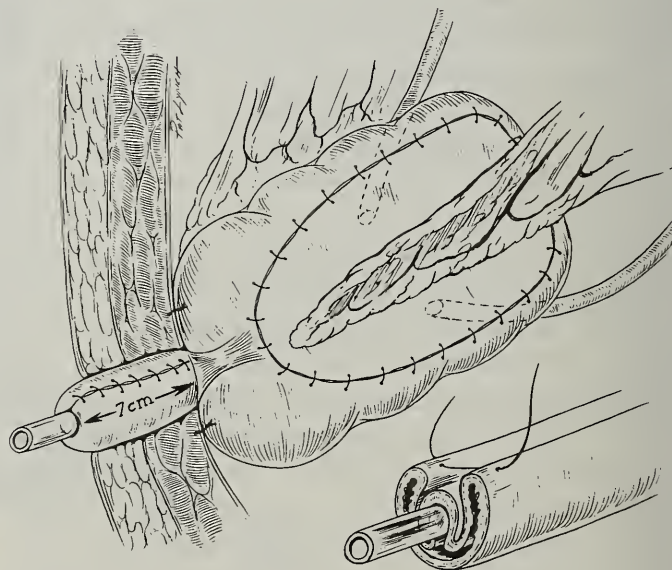


Figure 2
Ileocolonic pouch with continent abdominal stoma. Stomal segment reinforced with plicating silk sutures.

Thirteen patients (seven men and six women), ages 30-70, underwent continent diversion with an abdominal stoma. Eight patients had cystectomy for malignant dis-

ease, three had urinary diversions for neurogenic bladder dysfunction, and two for an exstrophy. All continent reservoirs were constructed from detubularized right colon and cecum with an ileal patch, as shown in Figure 2. In three of the patients, existing ileal and sigmoid conduits were detubularized and incorporated into the reservoir. The ureters were implanted into the colon in submucosal tunnels or, in two patients, implanted into the intussuscepted free end of the ileal patch to form a nonrefluxing nipple valve. The abdominal wall stoma was created from the terminal ileum. This was intussuscepted through the ileocecal valve to achieve continence in five patients and in three, the terminal 7 cm of the ileum was plicated over a 12 F catheter (Figure 2).¹⁵ All patients had estimations of serum electrolytes, blood-urea-nitrogen, creatinine, and urine cultures performed every six months postoperatively. Upper tract studies were performed six to 12 months postoperatively. Urodynamic studies, with measurement of reservoir capacity, maximum pressures, and radiographs to determine the presence of ureteral reflux, were performed six to 12 months postoperatively.

Results

The results with regard to postoperative complications, continence, freedom from infection, and metabolic acidosis have been very satisfactory. Only one serious postoperative complication occurred in this group of patients. This was an intraperitoneal leak from the suture line in the reservoir which required re-exploration, drainage, and repair. Three patients developed one episode of pyelonephritis requiring hospitalization and treatment with intravenous antibiotics postoperatively. The only other complication has been a prolonged ileus postoperatively in several patients that has resolved spontaneously.

It was found that the patients with detubularized right colon alone had capacities of only 300-500 ml and maximum pressures of between 60-100 cm of water. Patients, in whom a patch of ileum had been incorporated into the detubularized colon, had capacities of 400-600 ml with maximum pressures of 20-60 cm of water. Patients, in whom ileum was used exclusively, had capacities of 500-800 ml and generated maximum pressures under 15 cm of water. The significance of these observations is that all patients achieved daytime continence but only the nine patients with low pouch pressures have been continent at night. The two young males, under 16 years of age, have been unable to void and have had to resort to self-intermittent catheterization. All but one of the patients with an abdominal stoma are continent. No patients experienced any deterioration of the upper urinary tract as determined by either ultrasound or excretory urography. Reflux has occurred in five patients, four of these had their ureters implanted into a nipple in the proximal portion of the ileal patch so that this

method has been abandoned. No patients exhibited evidence of metabolic acidosis, electrolyte imbalance, or deterioration of renal function following continent diversion. Nine patients have sterile urine, eight of whom had bladder substitutes, the remainder have significant bacteruria. When possible, the pararectal nerves subserving potency were spared. Five male patients with bladder replacements and two with continent reservoirs are potent and have had satisfactory return of sexual function one to six months postoperatively.

Discussion

It has now been well demonstrated that detubularization of a bowel segment with reconstitution as a pouch greatly lowers the intraluminal pressure, and doubles the capacity.¹⁷ Moreover, small bowel reservoirs generate lower pressures than those made from large bowel.¹⁸ The ileocolonic pouch is anatomically easier to construct, and can be more readily retroperitonealized than those made from loops of ileum, and has proved very satisfactory for continent diversions with an abdominal stoma. However, an ileal pouch has been found to provide a more satisfactory bladder substitute.

Continent urinary diversion has evolved through several stages. The initial neobladders of detubularized right colon had lower capacities and generated higher pressures. These were functionally satisfactory, but patients had nocturnal incontinence for which they had to wear an appliance or get up frequently at night to avoid wetting. Patients with ileocolonic reservoirs that incorporate a segment of ileum had larger capacities and generated lower pressures.¹⁹ They did a little better with regard to nocturnal continence, however, the ileal pouch has proved to be the most satisfactory. These generate the lowest pressures with good capacities. The six patients that have had this type of neobladder are all continent both by day and night, although two of them get up once or twice at night to stay dry. They empty their pouches almost completely and they are abacteruric. This is now considered to be the procedure of choice. On occasion, an ileal pouch may not reach the urethra in patients with a short bowel mesentery, and in these cases it is necessary to use an ileocolonic pouch. This must, of course, be determined by careful measurement during the procedure.

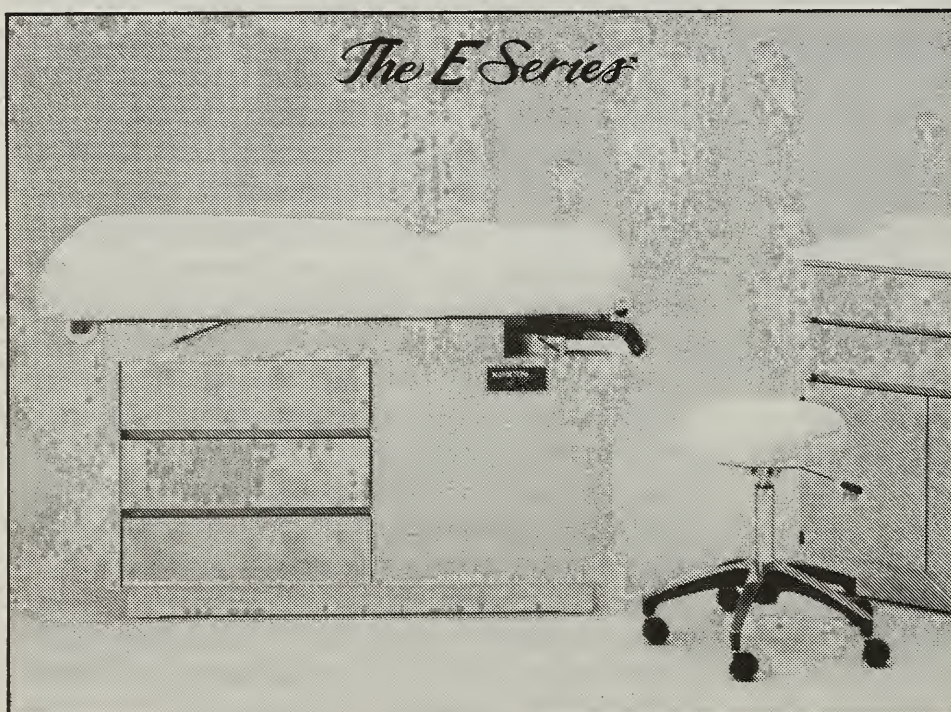
Continent urinary diversion represents a major advance in the rehabilitation of patients after cystectomy. Patients however need to be carefully selected as there are several contraindications to the procedure. Patients who have dysplasia or carcinoma *in situ* of the prostatic or membranous urethra are not candidates for a bladder substitute. Inflammatory bowel disease precludes the construction of a continent reservoir. Construction of a pouch prolongs the operation by two to three hours and extends the postoperative recovery by several days. It is, therefore, contraindicated in patients with significant medical problems or who are elderly. These patients are

best treated by simple ileal conduit diversion. It has been our experience that in properly selected patients, bladder substitution or a continent reservoir offers a greatly improved and more acceptable form of urinary diversion. The male patients who are completely continent have been restored to a normal life both physically and psychologically.

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Intraoperative Disseminated Intravascular Coagulation in a Patient with Ulcerative Colitis

TERENCE Z. WONG, M.S., JOHN P. WELCH, M.D., AND JOHN B. HOLT, M.D.

ABSTRACT—A patient with acute ulcerative colitis who developed acute disseminated intravascular coagulation during the course of a proctocolectomy is presented. Ulcerative colitis may represent a rare cause of acute disseminated intravascular coagulation.

ACUTE disseminated intravascular coagulation (DIC) is often precipitated by an underlying disease process such as infection, trauma, or shock. We present a case of acute DIC noted intraoperatively in a patient with ulcerative colitis. The association between DIC and ulcerative colitis is not well established. The present case suggests that active ulcerative colitis may have been a compromising factor which increased the patient's susceptibility to DIC during the course of a colectomy.

Case Report

A 71-year-old white female was admitted on 14 April 1988 for worsening diarrhea of two weeks' duration. She reported having 10 to 20 watery brown stools per day and occasional crampy abdominal pain. Her weight had dropped from 145 to 122 pounds over two months. One month prior to this admission, she had undergone an urgent left hemicolectomy and primary anastomosis at another hospital for presumed diverticulitis. The microscopic diagnosis of ulcerative colitis was made. The postoperative course was unremarkable. She had previously undergone cataract and lumbar disc operations. Medications at the time of admission included prednisone 40 mg q.d. (since the time of the hemicolectomy), Lomotil® 2.5 mg p.r.n., and meclizine 25 mg t.i.d.

Initially, stool assays were positive for *Clostridium difficile*, and the patient was given a 10 day course of Flagyl®. Although subsequent stool assays were negative, she continued to have symptoms. Intractable diarrhea continued in spite of several weeks of hospitalization and administration of steroids and parenteral

nutrition. Preparations were made to perform a total proctocolectomy and ileostomy. Prior to operation, she was afebrile with a white blood cell count of 11,600, hematocrit of 35.8, and platelet count of 262,000. The prothrombin time (PT) and partial prothrombin time (PTT) were 12.6 and 23.9 seconds, respectively, and she received vitamin K during the course of hyperalimentation. Liver function tests were normal.

At operation, the remaining colon was grossly involved with ulcerative colitis, and the proctocolectomy was begun. Several loops of small bowel were densely adherent to the colon near the site of the colonic anastomosis, although no gross abscess was encountered. It was speculated that she had sealed an anastomotic leak. After most of the colon and rectum had been resected, diffuse oozing of blood was noted in the pelvis, and no clots were visible. Control was achieved by packing the pelvis and applying pressure through the abdominal and perineal wounds.

Coagulation studies showed thrombocytopenia, a depressed fibrinogen level, and elevations of the PT and PTT suggestive of acute-onset DIC. Initially, the PT and PTT were 19.6 (normal 11.0-13.0 sec) and 58.6 (normal 38 sec) respectively; the thrombin time was 30 (normal 14-23 sec), and fibrinogen levels were less than 40 (normal 200-255/dl). The fibrin split products (FSP) were not measured during the procedure; levels were marginally elevated (10 mg/ml) immediately postoperatively. The acute fluctuations of the coagulation parameters are illustrated in Figure 1. Clot formation appeared and the bleeding stopped with continued packing and infusion of two units of fresh frozen plasma, 10 units of cryoglobulin, and six units of platelets. The total blood loss was estimated to be 5-6 L, replaced by 8,500 ml of crystalloid, seven units of albumin, two units of Hespan®, and 11 units of packed red blood cells. The perineum was closed using closed suction drainage of the pelvis. She received an additional two units of fresh frozen plasma in the recovery room.

Postoperatively, coagulation studies returned to normal and there were no further hematologic complica-

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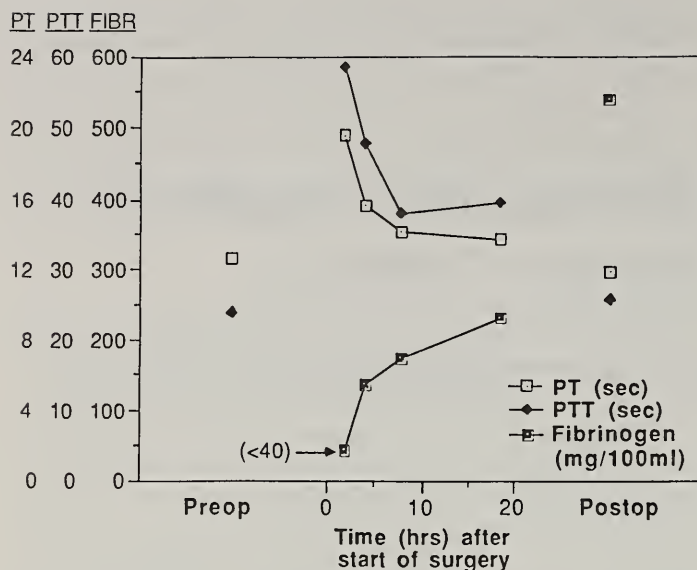


Figure 1

Changes in PT, PTT, and fibrinogen over time. Pre operative values for PT and PTT are shown to the left and were found to be markedly elevated during surgery. Fibrinogen levels were initially < 40 mg/dl. Fresh frozen plasma was given during surgery, and the values returned toward normal. Postoperative values obtained several days after surgery are shown on the right.

tions. The platelet count increased from 85,000 at 10 hours following the procedure to normal preoperative levels within eight days. Her recovery was prolonged secondary to a left peroneal nerve palsy which slowly resolved. She was weaned off Solu-Medrol® and discharged on 3 June 1988 (post operative day 17, 50 days after admission). Several weeks later she was hospitalized and treated by anticoagulation for deep venous thrombosis of the left lower extremity.

Discussion

The onset of acute DIC may be associated with a variety of underlying conditions, particularly infection, sepsis, shock, tissue injury, hepatic disease, or malignancy.^{1,2} Although the etiology of the acute-onset DIC observed in this case has not been firmly established, it appears likely that the underlying active ulcerative colitis was a contributing factor. Throughout her hospital course

the patient had no clinical evidence of sepsis, hepatic disease, or thrombosis.

There are few reports of DIC associated with ulcerative colitis. Muller et al³ presented a case of a patient with chronic ulcerative colitis who developed DIC which could not be corrected. The patient died from multi-organ failure; histologic examination of the bowel wall demonstrated large numbers of new fibrin thrombi. They concluded that this represented a univisceral Schwartzman reaction in the colon which had been sensitized by the active ulcerative colitis. Although they reported on the effects of the DIC, these authors did not speculate as to the cause of the DIC. Lake et al⁴ performed a prospective study of 12 patients with active inflammatory bowel disease who did not have symptomatic coagulopathies. Hematologic alterations found in these patients included thrombocytosis; abnormalities in platelet aggregation; elevations in fibrinogen, factors V and VII; and decreased antithrombin III. These coagulation parameters returned to normal when the underlying colitis was controlled. Detailed preoperative coagulation studies are not available for the current case report although thrombocytosis was not present.

We conclude that the acute DIC observed in this patient may represent an unusual complication of active ulcerative colitis. Although it was not evident prior to surgery, the active inflammatory bowel disease may have caused a mild coagulopathy which predisposed this patient to DIC when subjected to the additional trauma of operation with manipulation of the diseased bowel.

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Important Advances in Clinical Medicine

Emergency Medicine

The Scientific Board of the California Medical Association presents the following inventory of items of progress in emergency medicine. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers, or scholars to stay abreast of these items of progress in emergency medicine that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Emergency Medicine of the California Medical Association and the summaries were prepared under its direction.

Activated Charcoal—The First-Line Agent in Cases of Overdose

THE traditional approach to overdosed patients uses charcoal as a primary adjunct following gastric emptying with ipecac-induced emesis or gastric lavage. Over the past several years, several reports suggest that charcoal may be the preferred initial and sole agent of choice in most cases of toxic ingestions. Several studies suggest that using activated charcoal alone is superior to using either ipecac alone or gastric lavage. This includes a study that showed a greater reduction in gastrointestinal absorption of a standardized dose of salicylate by giving activated charcoal and a cathartic than either ipecac-induced emesis, gastric lavage, or the use of ipecac followed by charcoal. These data, in conjunction with a consideration of the difficulties and dangers associated with gastric lavage and the physical discomfort and risks of inducing emesis, support the primary use of charcoal in cases of overdose.

Activated charcoal is formed by the pyrolysis of carbonaceous organic materials. It is activated or oxidized by passing a stream of superheated (600° C to 900° C) steam or air over its surface. The resultant material has an extremely high surface area and a high affinity for a variety of substances. Standard activated charcoal has a surface area of 950 m² per gram, while the newer superactivated varieties have a surface area three to four times as great.

Beyond the proven efficacy of activated charcoal in limiting the gastrointestinal absorption of toxins, there is a growing body of evidence suggesting that repeated administration may hasten the elimination of already absorbed material. The elimination half-lives of theophylline, phenobarbital, carbamazepine, digoxin, nadolol, and dapsone have all been significantly shortened by repeated dosing with activated charcoal.

The risks associated with administering charcoal are minimal. The most common and generally most serious side effect is constipation, a problem that is avoided when it is given in conjunction with a cathartic agent, such as sorbitol. Charcoal suspension is gritty, which along with its black color, makes it less than palatable. This problem can be partially overcome by mixing it with a 70% sorbitol solution and having it sipped through a straw from an opaque container.

While most agents are absorbed by charcoal, there are some notable exceptions, including hydrocarbons, malathion, carbamate, alcohols such as methanol and isopropyl alcohol, and metals like lithium and iron. Concern about the use of charcoal in cases of acetaminophen overdose has been voiced because of its potential interference with antidotal therapy with acetylcysteine. While there is evidence that acetylcysteine is absorbed by charcoal, it appears that increasing the initial dose of acetylcysteine by 30% to 40% can compensate for this problem.

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Advances in Noninvasive Diagnosis of Deep Vein Thrombosis

THE diagnosis of deep vein thrombosis on clinical grounds in an emergency department is often difficult. Contrast venography is generally considered most accurate at detecting deep venous thrombosis of the lower extremity, but its use is complicated by an allergy to contrast media and a postphlebitic syndrome in as many as 5% of patients. Noninvasive testing has traditionally relied on audible Doppler ultrasonography and leg plethysmography. In combination they show 95% of cases of acute deep vein thrombosis seen by venography. The findings in as many as 15% of patients are falsely abnormal, caused by lymphedema, obesity, old deep vein thrombosis, hematoma, or popliteal artery aneurysm.

These disorders that mimic deep vein thrombosis can now be directly viewed by high-resolution ultrasound studies using advanced high-frequency transducers. Thrombus can be seen within the vein walls. Because organizing thrombus has a characteristic echogenicity, acute thrombosis can be distinguished from chronic thrombosis. Deep vein thrombosis is also suggested by an absence in vein compressibility by transducer-induced pressure on overlying skin. Using contrast venography as the standard, high-resolution ultra-sonography is 95% sensitive and 100% specific. It is seldom used alone because of breakthroughs in Doppler scanning.

Combining high-resolution ultrasonograms with the simultaneous evaluation of blood flow through the veins by Doppler ultrasonography is called "duplex" imaging. Although traditional audible Doppler marginally increases the sensitivity of high-resolution ultrasound studies to above 95%, it cannot distinguish deep vein thrombosis in obese patients with poorly defined high-resolution ultrasound images. Computerizing the Doppler scanning makes interpreting flow less dependent on the varying expertise of technicians. Measuring the Doppler shift of a gated, pulsed wave can yield the blood velocity at a single point in a single vessel. Presented graphically, this spectral analysis of flow versus time can reveal patterns of flow characteristics of degrees of stenosis. Duplex imaging using this pulsed Doppler technique has been successful at predicting stenosis at the carotid bifurcation and flow dynamics in the heart. Duplex imaging using pulsed Doppler for deep vein thrombosis of a lower

extremity shows it to be at least as sensitive as the traditional methods it will replace with increased specificities of 94% to 100% when compared with venography.

Like audible Doppler combined with plethysmography, duplex ultrasonography has a low sensitivity of 63% at revealing deep venous thrombosis limited to the calf. If this condition is to be treated, contrast venography is still indicated following a normal duplex ultrasonogram. The use of duplex ultrasonography results in fewer negative scans, however. It consistently detects disorders that mimic deep vein thrombosis such as hematoma, popliteal artery aneurysm, old deep vein thrombosis, superficial phlebectasia, and Baker's cysts missed by traditional procedures. This suggests that it has a direct contribution to the diagnosis of the cause of clinically suspected deep vein thrombosis. It can be used as an effective screening test to further reduce the need for contrast venography.

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Measuring Exhaled Carbon Dioxide in Cardiac Arrest

MEASURING the exhaled end-tidal carbon dioxide (EtCO₂) content by capnography is a useful procedure for continuously monitoring the ventilation in intubated and anesthetized patients. Recently this technique has also been found to be useful in cardiac arrest, where it is used not to monitor ventilation but as an indirect measurement of pulmonary blood flow (and thus cardiac output). There has previously been no technique that could be rapidly applied to a patient in cardiac arrest to determine the actual effectiveness of cardiopulmonary resuscitation (CPR) in terms of cardiac output, cardiac index, or perfusion pressure of the heart and brain, all of which are known to be critical to the success of resuscitation and long-term recovery. Capnometry solves this problem because it is noninvasive—although patients must be intubated—and can be applied in seconds by simply placing a special adapter in-line between the endotracheal tube and the ventilating device. In patients with cardiac arrest or severe shock, EtCO₂ measurements reflect not so much ventilation of the lungs as the delivery of carbon dioxide to the alveoli by the blood. During cardiac arrest, mixed venous CO₂ partial pressure often exceeds 100 mm of mercury because CO₂

generation by cells continues but dramatically reduced systemic circulation inhibits the elimination of gases by the lungs. (Arterial blood gas pressures at the same time may be normal and are not useful indicators of the cellular acid-base state in patients with cardiac arrest.)

Capnometry, therefore, reflects the ability of the circulation to deliver CO₂ to the lungs; in full arrest EtCO₂ levels are often 1 to 5 mm of mercury, compared with 40 mm of mercury in patients with normal circulation. In studies of both humans and animals, the EtCO₂ reading closely reflects cardiac output changes in 90 seconds or less. A sudden rise in the EtCO₂ value is often the first sign of the restoration of a perfusing rhythm, before the pulse can be palpated or before changes are noted on an electrocardiographic monitor. Similarly, the EtCO₂ level promptly reflects changes in the effectiveness of manual chest compression or the use of techniques such as interposed abdominal compression, making it possible for the first time ever to optimize CPR techniques for an individual patient to achieve the best perfusion pressures and the greatest likelihood of resuscitation. Determining the EtCO₂ level is helpful in identifying electromechanical dissociation in patients with substantial cardiac output despite the absence of pulses or a measurable blood pressure.

The EtCO₂ level may also have value in predicting the likelihood of a successful resuscitation. Critical coronary perfusion pressures must be achieved if a heart is to be resuscitated (and the brain preserved), and these are well correlated with the EtCO₂ content. The ability to achieve such perfusion pressures predicts the outcome of resuscitation in animals, so it is not surprising that the EtCO₂ level does so also. In animals, an EtCO₂ pressure of 10 mm of mercury or more seems to be needed to achieve resuscitation, and this value is associated with a coronary perfusion pressure of 30 mm of mercury, the minimum needed for successful resuscitation. A recent study in humans found that an initial EtCO₂ of 15 mm of mercury predicted the return of a perfusing rhythm with a sensitivity of 71%, a specificity of 98%, a positive predictive value of 91%, and a negative predictive value of 91%, independent of other factors such as the duration of resuscitation. Thus patients with pressures lower than 15 mm of mercury are highly unlikely to be resuscitated, although this still can occasionally happen. At present, clinicians can use this information as yet another indicator of the likelihood of resuscitation, like rhythm, witnessed arrest, bystander CPR, and other known predictors.

Capnography is not currently widely used in patients with cardiac arrest, but this will change as the price of the equipment decreases and clinicians learn the advantages of being able to monitor cardiac output and perfusion during an arrest. Such monitoring allows changing techniques of CPR and drug dosages to optimize resuscitation for an individual patient. It also allows an early identification of inadequate perfusion in a patient despite all attempts and which patients are unlikely to benefit from further resuscitation efforts.

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Cocaine Intoxication

COCAINE continues to be a major drug of abuse with serious medical, public health, and socioeconomic implications. It has been estimated that 10 million people are occasional or regular users of cocaine. In 1987 there were 1,700 cocaine-induced deaths in the United States. Given its extensive use and addicting properties, medical practitioners should be prepared to recognize and treat its numerous toxic effects.

Cocaine has multiple sites and mechanisms of action that include stimulating the release and blocking the reuptake of catecholamines at specific central and peripheral nervous system neurotransmission sites. This results in excess sympathetic stimulation and increases circulating catecholamines. The contribution of the local anesthetic actions of cocaine to systemic toxic effects is unknown. The clinical effects of cocaine toxicity cover a wide spectrum. Sudden death from cocaine use has been well described and probably occurs from an acute cardiac event or seizures. Although a commonly discussed toxic effect of cocaine is on behavior, only 29.2% of patients in one study presented with an altered mental state—agitation, hallucinations, or delusions—as their chief symptom. Medical complications can commonly involve numerous organ systems and include cardiovascular collapse, myocardial infarction, chest pain, arrhythmias, syncope, seizures, headache, asthma, abdominal pain, transient ischemic attacks, and stroke. Thus, cocaine use should be suspected in some patients when underlying causes of symptoms cannot be identified. A urine immunoassay can detect cocaine metabolites two days after use.

In recent years, the route by which cocaine abuse occurs has changed. Intravenous use has dramatically increased and has a higher potential to induce acute toxic effects. In addition, a nonion complexed form, "crack," is readily available. Unlike cocaine hydrochloride, crack when heated vaporizes and can be quickly absorbed through the lung, resulting in high serum concentrations.

The treatment of acute cocaine intoxication has been the subject of much debate. Pharmacologic agents have often been empirically selected to reverse abnormal behavior and symptoms and have not necessarily been directed toward the underlying mechanisms of cocaine

toxicity. In cases of severe agitation or seizures, diazepam, 5 to 10 mg, should be given intravenously and the dose titrated to a clinical response. Clinically significant palpitations respond well to the intravenous administration of propranolol hydrochloride. Patients having myocardial ischemia should be treated with nitrates and possibly other agents and admitted to hospital. Patients who present with a hypertensive crisis should be treated with intravenous agents such as phentolamine, propranolol, or sodium nitroprusside. Labetalol hydrochloride has been used as an alternative to propranolol, but its advantages have not been clearly proved. Recent studies on animals suggest that diazepam or propranolol may be superior to labetalol or haloperidol in preventing cocaine-induced death.

The treatment of patients who have become chronically dependent on cocaine includes a supervised detoxification program. Initial trials of multiple classes of pharmacologic agents have to date identified several tricyclic antidepressants as showing promise in treating addiction in habitual cocaine users.

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HIV Disease and Emergency Medicine

EMERGENCY medical personnel at all levels need to know about and take precautions against human immunodeficiency virus (HIV) disease because they are likely to see persons with HIV infection in the course of their work and are thus at an increased risk of occupationally acquired HIV infection. The latter results from both the large number and the nature of patients typically seen in the course of emergency medicine practice and the potential for intensive and uncontrolled exposure to blood and other bodily fluids in the course of rendering emergency care.

Recent data from Johns Hopkins University Hospital (Baltimore) have shown that nearly 8% of critically ill or injured patients visiting the emergency department were infected with HIV. The actual prevalence of HIV infection among emergency department patients in western states is not well defined, but several studies in this regard are now underway.

A wide range of HIV-infected persons are likely to be cared for, at least initially, by emergency medical personnel. The most common type of HIV-infected person to be seen in an emergency department is someone who may or may not be aware of his or her HIV status but who is asymptomatic for HIV infection and has an injury or non-HIV-related illness. Other HIV-infected patients

may, for various reasons, use the emergency department as their only source of care. And, of course, some will be in need of emergency care as a result of critical complications of the acquired immunodeficiency disease (AIDS). Patients may not be able to communicate information about their HIV status to emergency medical personnel or, for various reasons (including fear of discrimination), may choose not to share the information.

Recent data from California and elsewhere show that most patients with AIDS and HIV-seropositive persons continue to be from those groups generally recognized to be at high risk for HIV infection. These include homosexual and bisexual men, intravenous drug abusers, persons with hemophilia, recipients of HIV-contaminated blood, and sexual partners of all of these persons. Of the 17,164 AIDS cases reported in California as of January 1, 1989, nearly 90% were gay or bisexual men and 4% were intravenous drug abusers.

The overall prevalence of HIV infection in western states continues to be low. For example 0.016% of 1,550,693 units of whole blood donated in California between July 1987 and September 1988 was HIV seropositive. For the quarter ending September 1988, the HIV-seropositivity rate was 0.013%, which was down from a rate of 0.13% in the summer of 1985. Likewise, results from testing all babies born in California in July 1988 showed that only 36 of 43,301 (0.083%) had antibodies indicative of maternal HIV infection.

Data from acute care health facilities serving disproportionate numbers of higher risk persons indicate a relatively higher rate of infection. A 1987 HIV-seroprevalence survey of various types of publicly funded health facilities in 21 California counties—excluding San Francisco and Los Angeles counties—found 2.1% of 5,282 persons tested to be HIV seropositive, with the rate ranging from 1.1% in primary care public health clinics to 3.1% in sexually transmitted disease clinics. Similarly, the results of confidential HIV testing at 16 publicly funded family planning and primary care clinics from January through June 1988 showed 1.9% of 6,390 persons seropositive—0.33% of females and 6.04% of males. Further, 2.5% of 5,372 men and 3.1% of 807 women entering California's state prison system in the spring of 1988 were HIV positive. In each of these studies almost all of the seropositive persons belonged to recognized high-risk groups.

Despite the generally low prevalence of HIV infection in western states, the possibility of encountering HIV-infected persons in the course of emergency medicine practice and the consequences of acquiring the infection require that emergency medical personnel know the epidemiology and clinical manifestations of HIV disease and understand the indications for and complexities of HIV antibody testing. Emergency medical personnel also need to rigorously adhere to established infection control procedures, which assume that all patients are potentially infectious for HIV or other bloodborne pathogens.

Emergency medical personnel must assiduously guard

against accidental needle sticks because they present the greatest risk for health care work-related HIV infection. To date, about 80% of all health care workers suffering work-related HIV infection have acquired the infection from needle sticks. National data indicate that the risk of acquiring HIV infection following a needle stick contaminated with blood from a known HIV-infected person is approximately 0.5%. Health care personnel have also contracted HIV infection as a result of infected blood splashing on or otherwise contacting mucous membranes or open lesions.

All emergency services should have comprehensive ongoing programs to reduce accidental needle sticks and blood exposures; training in universal body substance precautions; specified policies and procedures for voluntary and confidential HIV antibody testing of patients from whom possible exposure to HIV may have occurred, as well as for exposed workers; and a comprehensive postexposure program, including counseling and consideration of the prophylactic use of zidovudine (AZT).

All health care personnel with exposure to blood from needle sticks should be reported as soon as possible to the Hospital Infections Program at the Centers for Disease Control (CDC), telephone number 1(404)639-1644, for possible enrolment in a postexposure AZT study and to develop a better data base for assessing risk. A baseline blood specimen also should be drawn as soon as possible after exposure and sent to the CDC. Similarly, Burroughs Wellcome Company is enrolling participants in a placebo-controlled study of the efficacy of the prophylactic use of AZT for health care workers who have sustained a needle stick (telephone, 1-800-HIV-STIK).

Consistently adhering to universal infection control procedures and addressing other HIV-related issues and concerns may be challenging in the emergency care setting and, therefore, must be anticipated and planned for.

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Paralyzing Agents in the Emergency Department

NEUROMUSCULAR blocking drugs have been used for many years in operating rooms to assist intubation and provide muscular relaxation. In the past five years, paralyzing agents have achieved increasing

use in emergency departments and have been introduced into the prehospital care setting. Paralyzing drugs are valuable in assisting endotracheal intubation in patients with head injuries, multiple trauma, drug overdose, and status epilepticus. They are also of benefit to patients who must be rendered motionless while undergoing emergent diagnostic tests such as computed tomographic (CT) scans or invasive procedures. Recent studies support the continued use of paralyzing agents in emergency departments.

Paralyzing drugs fall into two classes. The depolarizing neuromuscular blockers cause an initial depolarization at the neuromuscular end plate, characterized by muscular fasciculations. This is followed by complete irreversible muscular paralysis within 60 seconds, which lasts 2 to 5 minutes. The most commonly used depolarizing blocker is succinylcholine chloride. The dose in children and adults is 1 to 1.5 mg per kg body weight by intravenous push.

There are a number of serious adverse effects associated with using succinylcholine, including severe bradycardia, ventricular arrhythmias, and hyperkalemia. Other complications stem from fasciculations, such as regurgitation and aspiration, displacement of fractures, new fractures in osteopenic patients, and increases in intraocular pressure. Most possible complications of succinylcholine use can be avoided by carefully screening patients and using premedication. Administering atropine sulfate will prevent bradycardia; a priming dose of a nondepolarizing neuromuscular blocker will prevent fasciculations.

The nondepolarizing muscle relaxants (NDMRs) bind to the acetylcholine receptor at the neuromuscular end plate and competitively inhibit acetylcholine. They first cause muscular weakness followed by total paralysis within two to three minutes. Fasciculations do not occur. Paralysis lasts from 40 minutes to about 3 hours, depending on the dose and agent used. Paralysis may be reversible with the use of cholinesterase inhibitors such as neostigmine. The effects of NDMRs may be notably prolonged in patients with neuromuscular diseases such as myasthenia gravis. The NDMR drugs most commonly used are pancuronium bromide, atracurium besylate, and vecuronium bromide. Administering pancuronium (dose, 0.1 mg per kg) produces paralysis lasting about 60 minutes. The effects of atracurium (0.5 mg per kg given intravenously) and vecuronium (0.1 to 0.15 mg per kg intravenously) last 25 to 40 minutes. Vecuronium may be the ideal NDMR for emergency department use because it is short acting and causes minimal histamine release and hemodynamic changes.

Since 1986 at least four studies have been published to document the safe and effective use of neuromuscular blocking drugs in emergency departments. Emergency care physicians typically use succinylcholine to assist intubation in the subset of patients noted. The NDMR drugs are used to maintain paralysis in intubated patients

and to induce paralysis in patients who have head CT scans or invasive procedures. Despite the fact that paralyzing drugs were used almost exclusively in critically ill patients in these studies, reported serious complications were rare.

There are a number of prerequisites to the efficient, safe use of neuromuscular blockers by emergency staff. First, physicians must be expert in airway management, including the rare instance when a cricothyrotomy will be necessary. Patients who might be difficult to intubate and ventilate after paralysis—that is, those with epiglottitis, massive facial trauma, or airway obstruction—are not candidates for the use of paralyzing drugs. Each of the centers reporting success and safety with paralyzing drugs mandated special training by physicians and nurses in the pharmacology and complications of neuromuscular blocking drugs. Attention was given to premedication to minimize succinylcholine side effects, careful cardiac monitoring of patients during intubation, sedation of awake patients who were paralyzed, and assuring adequate oxygenation and ventilation once paralysis occurred.

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Pulse Oximetry in Emergency Medicine

PULSE oximetry is a noninvasive and continuous measurement of oxygen saturation (SaO_2). Oxygen saturation is measured by placing a special sensor on a patient's finger, toe, or nose. This sensor consists of a light-emitting diode—which projects two discrete wavelengths of light corresponding to saturated and unsaturated oxyhemoglobin—and a photodetector.

During the diastolic phase of a patient's pulse wave, a reference intensity of light is discerned. During systole the light intensity will vary with the amount of oxygenated hemoglobin present in the blood. Because the measurements are made using the change in light absorption between systole and diastole, no interference is present from anatomic aspects other than hemoglobin. Unlike its predecessor, the transcutaneous oxygen monitor, the pulse oximeter does not need to be "warmed up" or calibrated.

Oximetry was first conceptualized in the 1930s, but Leland Clark's introduction of the polarographic oxygen electrode in 1954 paved the way for the present-day use

of arterial blood gas pressures and the measurement of the partial pressure of oxygen (Pao_2). In 1983 oximetry was reintroduced in the form of pulse oximetry, and the technique rapidly gained initial acceptance through the monitoring of patients during anesthesia at risk for hypoxia. Since then clinical applications have expanded and presently include all patients at risk for hypoxia—such as those with respiratory failure, asthma, and endotracheal tubes in place—who would benefit from continuous oxygen saturation monitoring. The adequacy of airway management is also aided by pulse oximetry.

Many clinical and experimental studies support the fact that the noninvasive determination of SaO_2 has an accuracy of $\pm 2\%$; values of SaO_2 in the range of 70% to 99% are comparable to invasively derived laboratory values. Oxygen saturation, however, is related to the Pao_2 by the oxyhemoglobin dissociation curve, and patients who have an SaO_2 of 90% will have a resultant Pao_2 of 60 mm of mercury. Therefore, a small drop in the SaO_2 in the range of 90% to 99% will reflect a large drop in the corresponding Pao_2 . In addition, it should be remembered that pulse oximetry will be inaccurate in patients with hypothermia ($<35^\circ\text{C}$), hypotension (<50 mm of mercury), severe vascular disease, vasopressor therapy, abnormal pigmentation of the blood (such as bilirubin), or with abnormal hemoglobin (such as carboxyhemoglobin and methemoglobin).

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Thrombolytic Therapy for Acute Pulmonary Embolism

EVEN with prompt treatment, acute pulmonary embolism is associated with substantial morbidity and mortality. There has been considerable confusion regarding the indications for using heparin or thrombolytic agents for treating pulmonary embolism. Recent literature has, however, helped to clarify the role for each of these therapies and has emphasized the increased use of thrombolytic agents.

Thrombolytic therapy for acute pulmonary embolism has been shown to lyse clots, normalize pulmonary artery pressures, and restore pulmonary vascular perfusion faster than heparin therapy. Despite this clinical evidence, thrombolytic therapy remains underused. Although early studies suggested no difference in mortality between patient groups receiving thrombolytic therapy or heparin, more recent literature suggests there is a particular subset of patients who are most likely to benefit from thrombolytic therapy. This includes patients

with massive pulmonary embolism involving two or more lobar arteries, pulmonary embolism with hemodynamic compromise, or pulmonary embolism that has not responded to heparin therapy. Death in these patients is attributed to right ventricular failure due to persistent and notably increased pulmonary vascular resistance. Because of the early death associated with acute cardiovascular compromise, rapid clot lysis is desirable. The prompt use of a thrombolytic agent may facilitate the resolution of acute hemodynamic compromise in as little as two hours and lessen the likelihood of further decompensation. In contrast, heparin therapy prevents thrombus extension but does not cause thrombolysis, which may require a number of days, and therefore it does little to reverse the hemodynamic abnormalities. Thus, the choice between heparin and thrombolytic therapy may depend on the severity of hemodynamic or pulmonary compromise caused by pulmonary embolism.

Streptokinase and urokinase are the currently approved thrombolytic agents for the treatment of pulmonary embolism. Dosing recommendations include an initial bolus of the thrombolytic agent, followed by a maintenance infusion of the agent for 12 to 24 hours. Heparin should be used after thrombolytic therapy is discontinued when the thrombin time has returned to less than twice the baseline value.

Recombinant human tissue-type plasminogen activator (tPA), although presently lacking approval of the Food and Drug Administration for the treatment of pulmonary embolism, has been an effective therapy in experimental studies. In a recent clinical trial, infusing tPA resulted in significantly earlier clot lysis than using urokinase as assessed by pulmonary angiography, with a corresponding fall in the pulmonary artery pressure not seen in the urokinase-treated patients. Thus, tPA shows promise as a second-generation therapy for pulmonary embolism.

Despite careful patient selection, hemorrhage remains a major complication of thrombolytic therapy. Minor bleeding from puncture sites may occur and can usually be controlled with pressure dressings, but if major bleeding occurs, the thrombolytic agent should be discontinued, and fresh frozen plasma may be given. In addition, febrile and mild allergic reactions are common, particularly with the use of streptokinase, and generally respond to treatment with antipyretics and antihistamines.

The incidence of serious bleeding can be reduced by careful patient selection. Thrombolytic agents are contraindicated in patients with a history of stroke, a major neurosurgical procedure within the past two weeks, or active gastrointestinal hemorrhage. Relative contraindications are many and include uncontrolled hypertension, recent gastrointestinal bleeding, coagulopathy, and recent trauma or chest compressions.

Thus, there is now considerable supportive evidence that thrombolytic therapy decreases the acute morbidity of pulmonary embolism, at least in a subset of patients.

Further studies are needed to determine the optimal dose and infusion rate for these agents. Controlled studies are also needed to determine whether thrombolytic therapy compared with heparin therapy can reduce mortality and the risk of recurrence for all patients with pulmonary embolism.

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Military Antishock Garment Reevaluated

NO device in medical usage generates as intense controversy as does the military antishock trouser (MAST). When intravenous access is limited by the scope of practice of the prehospital care providers, MAST can easily be applied and a patient's blood pressure improved. Despite 20 years of use, this device was not objectively evaluated as to its effect on such variables as injury scores and, more important, mortality. A study of MAST using a statistically significant number of like injuries has yet to be done, but some recent studies cast new light on its use.

One group of investigators studied a mixed population of patients with both blunt and penetrating trauma in Houston's Emergency Medical System, which has rapid response and transport times. By alternating the days in which MAST was used, they showed no difference in the prehospital times, prehospital trauma scores, the amount of prehospital intravenous fluid administered (1,200 ml), or the ultimate mortality of these trauma patients. Even in a subset of patients with severe shock, defined as those with an initial blood pressure of less than 70 mm of mercury, no difference in mortality occurred. These patients theoretically would be most likely to benefit from MAST use but did not.

Seemingly well-designed, the Houston study was heavily weighted with cases of penetrating trauma. Only 18 of 342 patients sustained blunt abdominal trauma, an important subset that cannot be independently analyzed due to the small number of patients.

In San Francisco, a retrospective review of trauma patients treated with MAST compared with those in whom MAST was not available showed similar findings. Prehospital transport was not delayed and blood pressure was improved with the use of MAST, but no difference in mortality occurred. When dissecting these data for the subgroups of patients who might benefit most

from MAST, it was found that those trauma victims with initial trauma scores of 4 or less uniformly did poorly despite all efforts. Those with trauma scores between 5 and 8, however, had a lower mortality with MAST use.

Critics of MAST will point to these studies as proof that using MAST is ineffective. Admittedly the strongest argument against MAST use is that it does not correct the primary injury—that of hypovolemia. Rather, it masks it with an external device that increases peripheral vascular resistance and consequently blood pressure, leading to a false sense of security by delivering an artificially normotensive patient to an emergency department. Moreover, these studies cannot be extrapolated to non-urban trauma victims where prehospital transport times are longer. Indeed, one study suggests that a subset of trauma patients may benefit from MAST use even in the urban trauma system.

While these recent studies on MAST use in an urban trauma system with transport times of 15 minutes or less cast some doubt on its benefit, MAST use is still indicated to stabilize a patient for transfer to a trauma center from a community hospital and to control pelvic fractures or retroperitoneal hemorrhage (although this, too, has not been adequately studied). Stabilizing the blood pressure with MAST is not a substitute for adequate volume replacement in a trauma patient. Clearly, until more prospective evaluation of this device is undertaken, its use will continue to arouse controversy.

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Treatment of Near Drowning

MORE than 80,000 near-drowning episodes occur per year, and drowning remains the third leading cause of accidental death in the United States, claiming approximately 9,000 lives a year. Although the basic pathophysiology of near drownings is well established, the treatment of severe cases has been somewhat controversial. Recent studies help provide some answers.

The major physiologic consequences of near drowning are hypoxia, pulmonary edema, and respiratory and metabolic acidosis. Although there are mechanistic dif-

ferences between seawater and freshwater, the aspiration of substantial quantities of either results in a noncardiogenic pulmonary edema with respiratory compromise. Although changes can occur in serum electrolyte levels, hematocrit, and intravascular volume, these are rarely of clinical significance.

All drowning victims should undergo an attempt at resuscitation. The primary goal of that initial resuscitation should be the immediate initiation of effective respiratory support, possibly before actual extrication from the water. Attempts to drain water from the breathing passages are generally not advisable and may increase the risk of vomiting and aspiration. Therefore, the Heimlich maneuver should not be routinely used, being reserved for those situations in which persistent airway obstruction from foreign matter is suspected or all other attempts at artificial ventilation have failed.

All near-drowning victims should be subsequently evaluated at a hospital regardless of the stability of their symptoms at the scene, although the incidence of delayed or "secondary drowning" after an asymptomatic interval appears to have been exaggerated. All patients who subsequently required admission after saltwater submersion had signs of respiratory distress within the initial four hours. Whether this is also the case for freshwater submersion remains to be established. For those patients who have considerable respiratory distress, there should be a low threshold for early endotracheal intubation and the application of positive pressure ventilation. Temperature should be checked (by the rectum) to detect major hypothermia. Complete neurologic recoveries have been achieved after more than 40 minutes of submersion in cold water in patients as old as 11 years. Therefore, resuscitation efforts in a patient with hypothermia, despite prolonged submersion, should be extremely aggressive, including a consideration of immediate cardiopulmonary bypass.

For normothermic drowning victims, the prognosis is excellent for those patients who are seen with hemodynamic stability and neurologic responsiveness. Patients requiring cardiopulmonary resuscitation and who are initially neurologically unresponsive (Glasgow Coma Scale of 3 or 4) carry a poor prognosis. These patients require aggressive supportive intensive care with attention toward optimizing cardiac and pulmonary function. In addition, a number of controversial therapeutic interventions have previously been advocated in these patients. Many of these therapies, such as giving high doses of steroids, have recently been shown to have no effectiveness. While high-dose pentobarbital therapy may help to control intracranial pressure, it does not increase the number of survivors after near drowning. Although there is no doubt that patients who become hypothermic during a near-drowning episode have a better chance of surviving neurologically intact, there is no evidence that the therapeutic use of induced hypothermia increases the quantity or quality of survival. The routine use of intra-

cranial pressure monitoring in these patients is also being questioned but will require further study. The intensive care of these patients should focus on measures to prevent further aggravation of the original cerebral injury. The key to success in the treatment of near-drowning victims is providing aggressive and effective respiratory support at the earliest opportunity.

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Hypertonic Solutions in Resuscitating Patients in Hemorrhagic Shock

TRAUMA remains a major cause of morbidity and mortality; it is the leading cause of death in persons younger than 35 and the third leading cause of death in all age groups. It is estimated that half of all trauma deaths occur before reaching a hospital, many from lethal injuries that can be dealt with only by trauma prevention. Acute hemorrhage from reparable injuries is also a major cause of morbidity and mortality either owing to inadequate replenishment of the intravascular volume or from late effects of acute hypovolemia such as multiple organ-system failure.

With the introduction of trauma system planning, much has been learned regarding the initial treatment of trauma patients in both the prehospital and hospital phases. It is generally agreed that prehospital personnel contribute to patient survival by protecting the airway and the cervical spine and rapidly transporting patients to a trauma facility. Also agreed is that crystalloids—0.9% normal saline solution, lactated Ringer's mixture—are of little clinical benefit because frequently only small volumes can be infused during transport.

A growing body of evidence and experience indicates that infusing a small volume (4 to 5 ml per kg body weight) of a hypertonic saline solution (2,400 mOsm per liter) temporarily restores systemic hemodynamics as shown by increased blood pressure, cardiac output, and superior mesenteric artery flow. This effect is significantly prolonged when dextran 70 is added to the solution. Despite its transience, this improvement in flow results in increased survival, probably by delaying some of the deleterious effects of hemorrhagic shock—such as increased lactate and myocardial depressant factor activity.

The theoretic risks of administering hypertonic-hyper-

oncotic solutions have not been seen clinically in humans. Bleeding abnormalities and difficulties in cross-matching due to dextran, neurologic abnormalities, clinically significant hypokalemia, and rebleeding from injured vessels have not been seen in prehospital patients given a 7.5% sodium chloride and dextran 70 solution. The administration of hypertonic (3%) saline solution reduced intracranial pressures in hemorrhaged dogs with closed head injuries and was associated with less cerebral edema than the use of standard solutions.

The use of hypertonic-hyperoncotic solutions in the early resuscitation of trauma patients appears to be a promising addition to our ability to care for the severely injured in the difficult circumstances of the prehospital environment. Further data from current clinical trials should add considerably to our understanding of their role.

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Rapid Air Transport of Critically Ill Patients

THE documented medical benefits of the rapid delivery of critically ill patients to definitive care available only at tertiary care facilities has led to an increased emphasis on rapid aeromedical transport. Health care provision has been regionalized in urban and rural emergency medical systems in such subspecialty areas as trauma, obstetrics and gynecology, pediatrics, and cardiology. Despite the almost uncontrolled growth of helicopter programs and concerns about expense and safety, medical literature documentation of the benefits of aeromedical transport, and the desire of tertiary centers to expand their geographic referral base, has resulted in phenomenal expansion nationwide. There are 231 medical evacuation programs operating in 46 states and the District of Columbia. These include 156 hospital-based programs and more than 60 run by either the military or state and local governments.

Although data have been conflicting, no area of helicopter transport has been more closely studied than the

effects of air transport on improving survival in multisystem trauma patients. Studies have shown a statistically significant survival advantage in patients with serious injury transported from an accident scene by helicopter versus ground transport. The benefits to patient survival appear to be multifactorial, including not only rapid transport to definitive care but important therapeutic interventions such as endotracheal intubation, the transfusion of blood, and high-volume infusion.

Evolving higher standards of care for a patient sustaining an acute myocardial infarction and the small window of time in which such procedures as percutaneous transluminal angioplasty can be done or thrombolytic agents administered after an acute myocardial infarction have led to a closer evaluation of the safety of helicopter transport for cardiac patients. Despite documented increases in plasma catecholamine levels during transport, numerous studies during the past three years have found infrequent in-flight complications that were managed en route. Transient hypotension is the most common pre-flight and in-flight complication, followed by third-degree atrioventricular block and nonsustained ventricular tachycardia.

High-risk neonatal survival increases when delivery occurs in a perinatal center compared with survival when local delivery is followed by transfer. While many air-ambulance programs provide pediatric transportation for critically ill children, there is continued debate over the transfer of high-risk obstetric patients. A nationwide review of 315 helicopter transports of women in active labor revealed that, despite the fact that 72 were in the accelerated phase, there were no instances of in-flight delivery.

As studies increasingly define areas of possible benefit to critically ill patients, the optimal staffing of air ambulances and medical indications for air transport will be carefully delineated to further improve patient outcomes and safety in aeromedical transport.

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Update on Amphetamine Abuse

THERE has been a disturbing increase in the illicit production and abuse of amphetamines. One of the endemic areas for this increase has been the West Coast of the United States, particularly California.

Amphetamines have become the drug of choice for

adolescents in some communities. In one inpatient adolescent drug treatment unit, methamphetamine was listed as the drug of choice by about 80% of patients recently admitted. The reasons given for this preference include availability, low cost, and a longer duration of action compared with cocaine. Both oral and intravenous use are well documented in the literature. Less well documented are the users' preference to snort or smoke methamphetamine, and, as with "crack" cocaine, smoked methamphetamine is rapidly absorbed through the lungs.

Amphetamines obtained illicitly may contain D-amphetamine, methamphetamine, related amphetamine compounds such as 3,4-methylene dioxymethamphetamine, phenylpropanolamine, ephedrine, caffeine, and nonstimulant substances. Central nervous system effects may occur with minimal dosage, and an excessive amount of drug causes systemic catecholamine hyperstimulation. Amphetamines stimulate the release and block the reuptake of central catecholamines such as dopamine. Although the mechanism of action is similar to that of cocaine, some sites of action differ, and the half-life of amphetamine-induced euphoria is four to eight times longer than that of cocaine. Methamphetamine can be easily synthesized from ephedrine with inexpensive equipment. The end product of this synthetic process is a white to brown powder than can be snorted, smoked, injected, or swallowed. Because the synthesis process is usually clandestine, however, the product may contain a number of impurities. Such impurities can include toxic concentrations of lead, complex organic compounds that may be carcinogenic, or numerous amphetamine-related compounds.

Symptoms of acute intoxication are variable and can include hyperexcitability, confusion, hallucinations, and tachycardia. In severe cases, seizures and occasionally death have occurred. Amphetamines may produce a state mimicking paranoid schizophrenia and induce agitation and violence. In San Diego County in 1986, 40% of all homicides were methamphetamine related; cocaine was involved in 12% to 15%. This represented a 52% increase in methamphetamine involvement over the previous year. In San Bernardino County, the number of coroner's cases involving amphetamines is twice that of cocaine. Some emergency departments treat twice as many amphetamine-related problems as those of cocaine.

The treatment of an acutely intoxicated amphetamine patient should be directed toward ensuring an adequate airway and other supportive measures. Agitation should be controlled with the use of haloperidol, and cardiovascular hyperactivity responds to propranolol hydrochloride administration. Both of these drugs have been established as effective amphetamine antagonists in studies of animals. Although other agents such as diazepam have been used with success clinically, there are no controlled studies to validate their efficacy.

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Hydrofluoric Acid Burns of the Hand

HYDROFLUORIC acid is one of the most dangerous acids found in the workplace. Unlike other corrosives, a considerable amount of hydrofluoric acid remains undissociated when dissolved in water. In this uncharged state, it can penetrate deeply into tissues. Injury is mainly due to the interaction between fluoride and calcium, disrupting calcium-dependent processes and producing deep tissue necrosis and severe pain. This unique injury does not respond to standard burn therapy. Instead, current treatment involves applying calcium or magnesium after decontaminating by copious water irrigation. The choice of vehicle and the technique of administration depend on several factors: the surface area involved, the concentration of hydrofluoric acid, and the duration between exposure and treatment.

A minor burn is defined as an injury involving a few square centimeters of tissue (sparing the nail and nailbed), contact with a hydrofluoric acid concentration of less than 20%, and treatment soon after exposure. Treatment consists of bathing the hand in a 10% to 25% solution of magnesium sulfate and massaging the burn with a 2.5% calcium gluconate gel for at least 30 minutes. If pain persists after one to two hours of this therapy, the injured area is cautiously injected with a 10% calcium gluconate solution using a 27-gauge needle. The area infiltrated should extend 5 mm beyond the burn edge. A dose of 0.5 ml per cm² of involved tissue is recommended. For digital burns, no more than 0.5 ml per phalanx should be injected to avoid pressure necrosis.

A more aggressive approach is required for exposures involving hydrofluoric acid concentrations of greater than 20%, tissue contamination of more than a few square centimeters, or a long delay between contact with any concentration of hydrofluoric acid and treatment. Here, deep tissue injury is likely, and ointments or solutions cannot diffuse far enough to be effective. The initial management consists of calcium gluconate infiltration as described earlier. If the nailbed is affected, the nail must be removed before the calcium gluconate can be administered. Any bullae or necrotic tissue must be debrided.

In severe burns, those involving large areas of the hand, or if more than one nailbed is contaminated, infiltration with calcium gluconate becomes impractical. Instead, an intraarterial infusion of calcium gluconate is the treatment of choice. A radial arterial line is established using

a standard aseptic technique. Two grams of calcium gluconate are dissolved in 200 to 250 ml of a normal saline solution and infused by pump over four hours. The line is then maintained with heparinized saline for four to six hours. Should typical hydrofluoric acid pain return during this period, the patient is re-treated. After the second infusion, if avascular-appearing tissue remains, conservative debridement is carried out. This may include nail removal if the nailbed does not show improvement. This process continues until the patient is pain-free.

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Prehospital Intubation of Trauma Patients

ESTABLISHING an airway is the foremost priority in resuscitating any acutely injured patient. Most blunt trauma victims who require airway intervention have either sustained a major head injury or have respiratory distress due to thoracic trauma or hypovolemic shock. Establishing an airway in these patients can be lifesaving by alleviating hypoxia, lowering the intracranial pressure, and preventing aspiration.

Although there has been a trend in the prehospital setting to "scoop and run" with these patients, limiting the prehospital time expended, there is evidence that airway intervention in the field may increase survivability. Unfortunately, the need for establishing an airway in the field for a blunt trauma victim poses a dilemma to prehospital care providers. Although orotracheal intubation may be lifesaving, it has long been taught that this technique may induce or exacerbate a spinal cord injury in a patient with an unstable cervical spine.

Despite this belief, there are a number of trauma systems successfully using orotracheal intubation with "in-line stabilization" of the head and neck in blunt trauma patients both prehospital and in-hospital. In-line stabilization of the neck has been proposed as a protective measure against motion of an unstable cervical spine during orotracheal intubation. Although mounting experiential evidence supports the effectiveness of the technique, there is no scientific evidence that in-line stabilization affords any protection for an unstable spine during intubation. For this reason, alternatives to orotracheal intubation are being used in many emergency medical systems nationally.

The esophageal obturator airway is the most widely

used alternative that can be placed without neck manipulation and with little training. Despite years of experience, however, there is mounting evidence that as used in the field, ventilation and oxygenation are suboptimal. Both nasotracheal intubation and cricothyrotomy are being used in the prehospital setting in several major cities, but there has been little published on their practicality in that setting.

Other promising new airway adjuncts being studied include the pharyngotracheal lumen airway and the lighted-stylet guide for orotracheal intubation. Each of these appears to show promise, but, again, more clinical trials are necessary in the prehospital setting, and their effects on cervical spine mobility need to be clarified.

In the final analysis, until an effective alternative to orotracheal intubation can be developed and field tested, the risk of prolonged hypoxia, intracranial hypertension, and aspiration far outweighs the risk of inducing a spinal

cord injury in these already critically injured patients. Until then, the judicious use of orotracheal intubation with in-line stabilization under tight medical control appears to be as safe and effective as any method for establishing an airway in critically injured patients in the prehospital setting.

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More on the World's Longest Insulin Patient

SEVERAL months ago we published the story of the 68-year course of Mr. Theodore Ryder's diabetes mellitus (*Conn Med* February 1989;53:85-9). The account, written by Dr. Leroy H. Wardner, tells of the young patient receiving his first injection of insulin on 10 July 1922, about 20 months after the diagnosis was made. Mr. Ryder continues now under the care of Dr. David S. Wilcox of Hartford who has kindly provided an up-to-date account of his patient's medical history.

Dr. Wardner has also obtained photographs from the Archives of Sir Frederick Banting, Department of History, University of Toronto, showing the six-year-old Ted Ryder on the day he received his first insulin injection, quite possibly from Banting himself, and a second photograph taken one year later. These and Dr. Wilcox's account complete this medical success story.—Ed.

Dear Dr. Massey,

At the suggestion of Roy Wardner, I have enclosed a brief clinical summary of the current status of Ted Ryder whose medical history is truly remarkable.

Ted Ryder has had over 69 years of type 1 diabetes at this point and is in remarkable condition. He came under my care in November 1981 complaining of bad insulin reactions; at that time he was taking 9 units of regular and 16 units of protamine zinc insulin. He was admitted to Hartford Hospital in December 1981 and we changed his insulin to NPH alone to be given in the morning. He did well and was discharged on 2,300 calories and 34 units of NPH insulin. He was normotensive, showed diabetic dermopathy of the lower extremities, had absent pedal pulses and peripheral reflexes, and normal BUN, creatinine, and other laboratory values. He was seen in the office regularly but readmitted in October 1984 with gangrene of his right second toe. He was able to have a right second toe amputation which was uncomplicated and healed well. He went home on a split insulin regimen. Again he had normal laboratory values and his first hemoglobin A1C was 8.3%.

In July 1986 he was readmitted to Hartford Hospital with gangrene of the right third toe, which was treated by an open amputation of this toe with good healing. He went home on 44 units of NPH insulin in the morning only. Since then he has had some neuropathic problems with his feet, but they have healed well with local care. There have been no further hospitalizations.

He came in on 9 February 1989 for his annual physical examination with no specific complaints. He was looking forward to a trip to Europe with a friend in May of this year. He had no change in visual acuity; his last ophthalmological examination had been two years ago and slight cataracts precluded an adequate view of the fundus. However, he has never had significant retinopathy that has resulted in any visual impairment. A systems review was essentially within normal limits except for complaints of paresthesias in his feet. His habits included no smoking ever, occasional wine, and throughout his life he has walked extensively as he had never taken a driver's examination, and he walked from his apartment to town to obtain groceries and other needs.

On physical examination he weighed 170½ pounds and was 68¼ inches tall. Blood pressure 150/85. The only positive findings on general examination were a grade 3 basal systolic murmur, no pulses below his popliteals, absent knee and ankle jerks, and vibration sense diminished below his knees. He had interosseous atrophy of his hands and dermopathy of his lower extremities. His two amputations were well healed.

Laboratory tests were remarkable in that his BUN was normal at 16 mg/dl, creatinine normal at 1.2 mg/dl, electrolytes were entirely within normal limits, cholesterol 206 mg/dl, triglycerides 92 mg/dl, and HDL 51 mg/dl. White count 5,300, hematocrit 42, and indices and differential were normal; his urinalysis showed no albumin. His random blood sugar was 229 mg/dl two hours after breakfast.

His current insulin dose is 40 units of NPH once a day. He has had no severe insulin reactions and only with a meal delay does he have a mild reaction. He takes no oral



July 10, 1922 - Weight 27 pounds, the day he received his first injection of insulin.

medication except vitamins. He does no monitoring at home—urines or blood sugars—and at this point in his life with his remarkable status, I have not used any pressure to have him do home blood sugar monitoring. His last hemoglobin A1C was moderately elevated at 8.4% in May, 1987.

His electrocardiogram has been normal and unchanged since I have followed him. I specifically have noted no cardiovascular symptoms, neither angina nor claudication.

My impression is that Ted is remarkably free of



July 10, 1923 - Weight 45 pounds.

problems after 69 years of diabetes and 67 years on insulin. He shows evidence of neuropathy and may have some background retinopathy but his vision is entirely functional. Most remarkably he has no cardiac symptoms, never had a TIA or cerebrovascular accident, his neuropathy has resulted in prior toe amputations, and he has no proteinuria and has a normal BUN and creatinine. Likewise his lipids are normal.

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Hartford

Babesiosis — Connecticut

CENTERS FOR DISEASE CONTROL, ATLANTA

SINCE August 1988, six cases of babesiosis—a rare protozoan parasitic disease—have been reported to the Connecticut Department of Health Services (CDHS); only two cases thought to have been acquired in Connecticut were reported before 1988.

The first person became ill in August 1988; onset of illness in the other five persons occurred between late June and mid-August 1989. Ages ranged from 68 to 86 years; five were men. All six persons had fever, headache, and fatigue. Two of the patients were taking oral corticosteroids for chronic obstructive pulmonary disease; none was otherwise immunosuppressed, and none was asplenic. Four patients were treated with both quinine and clindamycin; one received quinine without clindamycin; the sixth received no specific therapy for babesiosis. All six are now asymptomatic, and their parasitemia has cleared.

Five of the patients (including the first case-patient) lived within three miles of each other; the sixth lived 22 miles away. None of the patients gave a history of recent travel to areas with known endemic babesiosis, and none had received blood transfusions before becoming ill. Gardening near the home was the principal outdoor activity of four persons; the other two walked in fields near their homes. Only one person recalled being bitten by a tick before becoming ill, and all six had observed mice in the areas around their homes.

For all six persons parasites were detected on peripheral blood smears. In addition, each had IgG antibody titers to *Babesia microti* of $\geq 1:1024$. *B. microti* was isolated (by hamster inoculation) from the blood of two patients and from eight (73%) of 11 mice trapped near four of the patients' homes. A statewide survey conducted in 1976-77 detected *B. microti* antibodies in mice collected in four of 22 sites.¹ Three of these four sites are within 20 miles of five of the patients' homes and within 45 miles of the other patient's home.

The CDHS has alerted Connecticut physicians to the

presence of a newly recognized focus of babesiosis within the state and has advised physicians to report all suspected cases. Surveys are planned to determine the extent of the infection in humans and rodents.

Reported by: J.J. Gadbaw, M.D., Lawrence and Memorial Hospital, New London; J.F. Anderson, Ph.D., Connecticut Agricultural Experiment Station, New Haven; M.L. Caritter, M.D., J.L. Hadler, M.D., State Epidemiologist, Connecticut Department of Health Services, Division of Parasitic Diseases, Center for Infectious Diseases; Division of Field Services, Epidemiology Program Office, CDC.

Editorial Note: *Babesia* is a protozoan parasite of red blood cells. In the United States, babesiosis is most commonly caused by *B. microti*. Babesiosis was recognized in the Northeast in the 1960s and is endemic in Nantucket, Martha's Vineyard, Shelter Island, and parts of Long Island.²

In humans, *B. microti* infection may be subclinical or may present as a febrile illness with constitutional symptoms and anemia. Manifestations are most severe in elderly, immunosuppressed, or asplenic persons.³

The natural hosts for *B. microti* include the white-footed mouse and the meadow vole. Tick bite by *Ixodes dammini* is the usual source of human infection. In addition, infection can be transmitted by blood transfusion.³ Entomologic surveys have detected increases in *I. dammini* and its spread to new areas.⁴ Physicians should be aware that babesiosis could occur in areas where *Babesia* was not previously considered endemic.

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Oral Complications of Cancer Therapies: Diagnosis, Prevention, and Treatment

NATIONAL INSTITUTES OF HEALTH

Introduction

MORE than one million Americans will develop cancer during 1989. These newly diagnosed malignancies will include 228,000 gastrointestinal cancers, 155,000 lung cancers, 143,000 invasive breast carcinomas, 40,000 lymphomas, and 27,000 cases of leukemia. Also included are the estimated 30,000 cases of oral and oropharyngeal cancer.

Management of many malignancies requires local or radical surgical excision. Other forms of cancer treatment may be employed, eg, radiation therapy, chemotherapy, and bone marrow transplantations. Unfortunately, more cancer treatments affect normal as well as neoplastic cells and tissues. As treatments have become more intensive and therapeutically successful, the effects on normal tissues have increased. The oral cavity is a very frequent site of such side effects. As a result of treatment, as many as 400,000 patients may develop oral complications that may be acute or chronic in nature. The more powerful the treatment modalities, the greater the risk of morbidity.

At a minimum, oral complications are painful, diminish the quality of life, and may lead to significant compliance problems, often discouraging the patient from continuing treatment. Cancer treatments may produce a breach in mucosal integrity, allowing pathogenic organisms to spread systemically, further compromising the patient. At times, levels of oral morbidity may interfere with oncologic therapy, necessitating suspension of therapy until such complications resolve.

Side effects of radiation therapy to the head and neck may be noted as early as the first week. The potentially

devastating occurrence of osteoradionecrosis in the irradiated patient has yet to be widely addressed in terms of multicenter, collaborative studies. The prevention and management of this and other oral complications remain as incompletely resolved clinical issues.

Bone marrow transplantation (BMT) is an evolving cancer management with frequent oral complications. Although BMT was once considered desperate and reserved for treatment of end-stage leukemia, it is now used routinely as an effective tool for treatment of several other cancers. Before and after actual transplantation, the possibility of secondary dysfunctions of the oral cavity exists. The stomatotoxicity of chemotherapy and total body irradiation, the associated risk of early septicemia from oral organisms, and the possibility of acute and chronic graft-versus-host disease all may affect the ultimate treatment outcome. Literature on the subject is sparse, and there are few well-documented studies demonstrating the efficacy of treatment of oral complications of BMT.

Pretreatment therapy for oral complications can positively affect the outcomes of cancer treatment. All members of the cancer treatment team should be fully informed of the oncologic treatment plan. Oral care should be initiated at the outset of cancer treatment with the goal of reducing morbidity and in many instances improving compliance.

The above clinical considerations prompted the formulation of several questions that served as the structural framework for this 2-day conference. The sponsors of this conference were the National Institute of Dental Research, the National Cancer Institute, the Office of Medical Applications of Research, and the Clinical Center of the National Institutes of Health, and the Food and Drug Administration. Speakers, panelists, and members of the audience delivered and discussed new data, clinical experiences, and existing information that was used to formulate the statement in response to the

From the Office of Medical Applications of Research, National Institutes of Health, Bethesda, Md.

Reprint requests to Office of Medical Applications of Research, Bldg 1, Room 260, National Institutes of Health, Bethesda, MD 20892 (William H. Hall). Bibliography, prepared by the National Library of Medicine, is available from the same address.

following questions:

- Is there a role for pretherapy interventions affecting the oral cavity in reducing the incidence of oral complications in the cancer patient?
- Which pretreatment strategies are optimal to prevent or minimize oral complications?
- What are the most effective strategies for management of acute oral complications occurring during cancer therapy?
- What are the indicated strategies for management of chronic oral complications following cancer therapy?
- What are the directions for future research?

Absent from the discussion and consensus document are the broad and important areas of postsurgical management, including surgical reconstruction and maxillofacial prosthodontic treatment. Both the surgical and prosthodontic considerations were thought to be significant but beyond the scope of this conference.

What are the Oral Complications of Cancer Therapies?

Surgical removal of anatomical structures in the head and neck region compromises oral function to varying degrees. In chemotherapy, most complications are the result of myelosuppression, immunosuppression, and direct cytotoxic effects on oral tissues. Major clinical problems in the oral cavity that are associated with chemotherapy include mucositis, local or systemic infection, and hemorrhage. Total body irradiation and radiation for head and neck cancer have both direct and indirect effects on oral and related structures. The oral complications of radiotherapy to the salivary glands, oral mucosa, oral musculature, and/or alveolar bone include growth and developmental abnormalities, xerostomia, rampant dental caries, mucositis, taste loss, osteoradionecrosis, infection, dermatitis, and trismus. It is the recognition of the risk of these complications and their relation to outcome that prompts the discussion and necessitates agreement on the best means of management.

These complications result from the aggressive treatment of cancer; many would not occur if cancers could be detected and treated at an early phase. The emphasis of this conference on the prevention and treatment of complications should not detract from the basic goal of prevention and early detection of cancer.

Is There a Role for Pretherapy Interventions Affecting the Oral Cavity in Reducing the Incidence of Oral Complications in the Cancer Patient?

Oral complications resulting from anticancer therapies can significantly affect morbidity, the patient's tolerance of treatment, and the quality of life. Death can sometimes result from severe oral complications. There is a role for pretherapy intervention in reducing the incidence and severity of oral complications. Data presented at the conference convincingly demonstrated that appropriate interventions can significantly lessen morbidity and possibly decrease mortality.

There is evidence that preexisting oral disease unrelated to cancer or therapy may increase the risk of oral complications. Before the initiation of cancer therapy, a comprehensive pretreatment dental evaluation is mandated. The following objectives should be fulfilled:

- Establish baseline data with which all subsequent examinations can be compared.
- Identify risk factors for the development of oral complications.
- Develop strategies to avoid treatment complications during and following cancer therapy.
- Perform necessary dental treatment to reduce the likelihood of oral complications induced by cancer treatment.

Which Pretreatment Strategies are Optimal to Prevent or Minimize Oral Complications?

There are many pretreatment strategies available to minimize or prevent oral complications. These afford the clinician a unique opportunity to ameliorate the side effects induced by cancer therapy. Pretreatment strategies include evaluation, treatment of preexisting dental disease, patient and family education and counseling, prevention of oral mucosal infections, interventions to modify salivary gland dysfunction, reduction of iatrogenic and disease-related neutropenia, and prevention of mucositis.

A comprehensive patient examination is paramount to identify preexisting oral problems that have the potential to affect the course of cancer therapy. To satisfy the objectives of the examination, the following data must be obtained in patients at risk for oral complications: cancer diagnosis, medical history, dental history, dental charting, periodontal charting, appropriate radiographs, and nutritional status. Some clinicians may wish to include volumetric assessment of resting and stimulated whole saliva. Additionally, study models could be obtained where deemed appropriate.

Potentially complicating oral disease should be identified and corrected as early as possible before commencement of anticancer therapy. Significant problems include poor oral hygiene, third molar pathology, periapical pathology, periodontal disease, dental caries, defective restorations, ill-fitting prostheses, orthodontic appliances, and any other potential sources of irritation.

Sources of infection and irritation are important targets for early intervention. At the initial dental evaluation, all cancer patients should undergo thorough oral hygiene procedures, including root planing, scaling, and curettage. These procedures are beneficial in reducing the incidence of oral complications by removing bacteria that can result in local and systemic infection. The neutrophil and platelet count must be considered before any patient undergoes an invasive procedure. This intervention should be supplemented by daily plaque removal including toothbrushing with a fluoride toothpaste and flossing, if this can be tolerated by the patient. Addition-

ally, the use of topically applied fluorides and chlorhexidine mouth rinse has shown clinical benefit in the prevention and control of dental caries and plaque.

Dental foci may be potential sources for systemic infection and should be eliminated or ameliorated. Treatment may include dental extractions or endodontic therapy. Ideally, dental procedures, but especially dental extractions, should be completed at least 14 days before cancer therapy, if the patient's condition permits.

Most of the pretreatment as well as treatment protocols aimed at preventing or ameliorating oral complications of anticancer therapy require patient adherence to prescribed oral hygiene procedures. Patient and family education, counseling, and motivation are critical to the success of any preventive pretreatment strategy. The patient must be cognizant of the potential side effects of the anticancer regimen. The rationale for pretreatment strategies must be explained to encourage patient adherence to the therapy.

Bacterial and fungal surveillance cultures are not necessary for routine patient management. Suspicious lesions should be cultured. The use of prophylactic acyclovir should be considered in seropositive patients at high risk for reactivating HSV infection, ie, the bone marrow transplant patient and possibly other patients with prolonged, profound myelosuppression. The prophylactic use of acyclovir in patients who are at lower risk probably is not indicated and carries a low risk of development of acyclovir-resistant strains. Although acyclovir is a relatively safe drug, it may have side effects, including renal dysfunction and, rarely, central nervous system toxicity.

Salivary gland dysfunction is one of the most common sequelae of head and neck cancer treatment. At present, there are no agreed-upon pretreatment strategies to prevent or minimize xerostomia. However, studies are being conducted to evaluate various techniques, including radioprotective agents and drugs such as pilocarpine that can maintain or enhance salivary gland function during radiation. The latter approach appears to be the most promising for future clinical applications.

Pretreatment strategies to reduce iatrogenic and disease-related neutropenia in cancer patients are under investigation. A pilot trial of recombinant granulocyte colony stimulating factor (rhG-CSF) administered to patients during chemotherapy resulted in restoration of the neutrophil count and function and a decrease in severity of mucositis. Mucositis is a universal and often painful consequence of chemotherapy and radiotherapy to the head and neck. At the present time, there is no other agent that is effective in preventing therapy-related mucositis. Randomized clinical trials addressing this problem are in progress.

What Are the Most Effective Strategies for Management of Acute Oral Complications Occurring During Cancer Therapy?

Acute oral complications occurring during treatment

are related to the type of cancer and forms of therapy. These problems have several different clinical presentations including: mucosal inflammation and ulceration of varying etiologies, oral candidiasis, viral and bacterial infections, dental or periodontal infections, and mucosal bleeding. Treatment of oral infections is important to reduce the debilitating symptoms associated with these lesions and to minimize the risk for developing systemic bacterial or fungal infections.

Mucosal Inflammation and Ulceration

Radiation therapy for head and neck cancer causes mucositis, which can progress from erythema to ulceration. Chemotherapy given in conjunction with radiation may accelerate the onset and increase the severity of radiation mucositis. No currently available drugs can prevent mucositis. Distinguishing radiation-induced mucosal changes from other similar appearing lesions is suggested by their occurrence within the radiation fields. Appropriate cultures and smears may be necessary to diagnose fungal infection in the presence of radiation mucositis. There are several alternative drugs for antifungal therapy; however, prolonged dental contact with nystatin solution, nystatin pastilles, or clotrimazole oral troches may lead to dental caries because they contain large quantities of sugar.

Chemotherapy that does not result in profound myelosuppression can nevertheless cause mucosal ulceration by directly damaging the epithelium. The most commonly associated agents are antimetabolites such as methotrexate, 5-fluorouracil, and purine antagonists. Antitumor antibiotics, hydroxyurea, VP-16, and procarbazine can also cause nonspecific mucosal ulceration.

Oral ulceration may be associated with the underlying cancer, particularly acute leukemias, and with severe neutropenia from any cause. In these cases, the diagnosis is dependent on recognizing the association and ruling out infection. In a high percentage of patients undergoing BMT, oral mucosal lesions may occur as part of acute or chronic graft-versus-host disease. These lesions may take several forms, including erythema, lichenoid change, ulceration, or hyperkeratosis. Therapy depends on management of the underlying disease.

There are also many untested topical oral preparations that claim to reduce the symptoms of oral mucositis. The efficacy and safety of these agents have not been established. Ingredients in these combinations have included: diphenhydramine hydrochloride, kaolin and pectin, magnesium sulfate, antacids, sucralfate, corticosteroids, dyclonine, and lidocaine hydrochloride. In patients having trouble eating because of severe oral mucositis, use of local and/or systemic pain control may be necessary.

Viral Infection

Herpes simplex virus (HSV) is the most common viral pathogen associated with oral lesions in patients receiving myelosuppressive chemotherapy or BMT. A large

number of patients have had prior infection with HSV as evidenced by the presence of HSV antibodies in the serum of 30% to 100% of adults in the general population. Under conditions of immunosuppression, the latent virus often reactivated, leading to severe oral, and occasionally, disseminated infections. Approximately 50% to 90% of BMT patients who are seropositive for HSV will develop HSV infections, usually within the first five weeks after transplantation. Similarly, a large proportion of patients with acute leukemia or others receiving intensive chemotherapy will reactivate HSV during periods of immunosuppression.

In contrast to HSV infection to immune competent individuals, HSV infections in the immunocompromised host are associated with severe ulcerations that may occur on any oral mucosal surface. In immunocompromised patients, the mucositis associated with HSV is more painful, severe, and prolonged than mucositis uncomplicated by viral infection. HSV ulcerations may be the portal of entry for bacterial and fungal pathogens. In addition, the virus may cause esophagitis and, rarely, disseminated infection.

Herpes simplex infections are often difficult to diagnose on clinical grounds alone because it may be difficult to differentiate them from mucosal lesions of other etiologies. Due to the morbidity associated with HSV infections and because of the availability of effective antiviral therapy, it is advisable to obtain viral cultures in immunosuppressed patients. Cytologic and newer diagnostic tests for the presence of viral antigens may be useful for rapid diagnosis of HSV infections. In patients in whom the presumptive diagnosis is oral HSV infection, it is reasonable to initiate therapy with either oral or intravenous acyclovir while awaiting the results of viral diagnostic tests. The intravenous route may be preferred in severe infections and in patients unable to take oral medications.

Oral Candidiasis

Several types of oral mucosal lesions are caused by overgrowth and infection by *Candida* species, including pseudomembranous candidiasis (removable white plaques), chronic hyperplastic candidiasis (leukoplakia-like white plaques that do not rub off), chronic erythematous candidiasis (patchy or diffuse mucosal erythema), and angular cheilitis. Fungal cultures, potassium hydroxide, and gram-stained smears are helpful diagnostic tools. The white, raised, removable plaques of the pseudomembranous form of candidiasis are most obvious to the examiner. Diagnosis can be confirmed by a potassium hydroxide smear. These organisms may infect other sites in the gastrointestinal tract and cause esophagitis or diarrhea. In neutropenic patients, mucosal infection with *Candida* may lead to systemic infection.

Topical forms of therapy for oral candidiasis include nystatin and clotrimazole. Pseudomembranous candidiasis can usually be treated with topical nystatin. Lesions

of chronic oral candidiasis usually require much longer treatment, especially in patients with severe chronic xerostomia resulting from head and neck radiation therapy. In more extensive infections, such as esophagitis, oral ketoconazole may be effective. For infections not responding to the above measures, a course of low-dose intravenous amphotericin B may be indicated. Disseminated candidiasis should be managed with intravenous amphotericin B.

Bacterial Infections

Bacterial organisms in the mouth can cause localized infections, including acute sialadenitis of major salivary glands, periodontal abscess, pericoronitis, or other mucosal or dental infection. These problems usually require empirical treatment with selected antibiotics, but gingival and periodontal lesions usually require additional treatment by local debridement of bacterial plaques.

Systemic infection is a major cause of morbidity and mortality in neutropenic patients. In some cases, the oral cavity may be the portal of entry for bacterial pathogens. Whether a source of infection can be identified or not, empiric, broad-spectrum antibiotic therapy must be initiated promptly in the febrile neutropenic patient. There are several different antibiotics or antibiotic combinations that may be appropriate in this setting. Because pseudomonas infections are associated with a high mortality rate in neutropenia, the empiric regimen should include antibiotics that adequately treat this organism.

Mucosal Bleeding

Mucositis due to any cause may be accompanied by oral bleeding, especially in severe thrombocytopenia caused by leukemia, lymphoma, or myelosuppression. Disseminated intravascular coagulation is another important potential cause of thrombocytopenia or hemorrhage in immunocompromised patients. Severe thrombocytopenia may predispose patients to bleeding from routine mechanical oral hygiene procedures. In addition, these procedures may increase the risk of septicemia in patients with severe neutropenia. In these patients, dental plaque can be effectively managed by daily mouth rinsing with a chlorhexidine solution.

What Are the Indicated Strategies for Management of Chronic Oral Complications Following Cancer Therapy?

Therapeutic modalities used in the treatment of malignancy can result in changes in healthy tissues arising long after treatment has been completed. These sequelae must be addressed for the remainder of the life of the patient.

Xerostomia is an example of such a problem in patients receiving therapy for head and neck or other forms of cancer. Total body radiation, and especially local radiation to oral structures, may irreversibly affect the production of saliva by both the major and minor salivary glands. The magnitude of this problem is dependent upon the radiation dose and volume of tissue exposed. Significant xerostomia is not as frequently

encountered in patients treated with chemotherapy. Concomitantly administered medications such as psychotropic and antiemetic medications should be evaluated for their xerogenic potential.

Chronic graft-versus-host disease is associated with xerostomia. Painful lichenoid lesions can also develop in these patients and thus compromise therapy unless controlled by immunosuppressive therapy. Long-term cyclosporine can lead to gingival hypertrophy.

There are no widely employed diagnostic criteria to estimate the degree or extent of xerostomia. We are still primarily dependent upon subjective impressions by both patient and clinician. A dry mouth may affect speech, taste, nutrition, and the patient's ability to tolerate dentures or other oral prostheses. Saliva also contains antimicrobial compounds and is important in the mechanical removal of pathogens from the mouth. As a consequence of decreased saliva production, there may be an overgrowth of caries-producing organisms. This may have devastating effects on the dentition, even in individuals without prior history of dental caries. In addition, an increase in the frequency of candidiasis and in the severity of gingival/periodontal infections has been observed in some patients.

Management of chronic xerostomia involves a combination of strategies:

- Continuous maintenance of effective oral hygiene to reduce colonization and proliferation of oral pathogens.
- Use of water or saliva substitutes to keep the mouth moist.
- Stimulation of residual salivary parenchyma to produce more saliva.

Intensive oral hygiene methods and the use of an adequately protective topical fluoride are the most important methods of preventing the dental complications of xerostomia.

In terms of saliva substitutes, several preparations are being tested. Ideally, these should reduce patient discomfort, be long-lasting, and should substitute for salivary components that are necessary for the maintenance of mucosal and hard tissue integrity. There is a need for more effective preparations and more data on the long-term benefits of this form of therapy.

Sialogogues, such as pilocarpine and anetholetrithione, alone or in combination, are being tested to stimulate the formation of saliva. The data suggest that this approach benefits patients who have some residual functional salivary tissue, resulting in a steady increase in salivary flow and symptomatic improvement. These drugs appear to be well tolerated; side effects are minimal and readily controlled. The effectiveness of sialogogues in reducing the long-term ravages of xerostomia (eg, radiation caries) has not been documented.

The long-term effects of radiation therapy to the head and neck region include obliterative endarteritis with

resultant tissue ischemia and soft tissue fibrosis. These changes may progress with time and never resolve. Surgical wounds in the irradiated area heal poorly and chronic radiation ulcers may develop. Fibrosis of the muscles of mastication and the temporomandibular joint, while uncommon, may result in trismus. However, recurrent tumor must be ruled out.

Osteoradionecrosis (ORN), a relatively uncommon clinical event, is a consequence of hypovascularity, the cytotoxic effects of radiation on bone-forming cells and tissue, and is associated with hypoxia of the affected bone. As a consequence, when bone is injured, it is unable to heal and becomes susceptible to secondary infection. This process can progress to pathologic fracture, infection of the surrounding soft tissues, and oral-cutaneous fistula formation. It is characterized by severe, constant pain. The risk of developing ORN is lifelong. Chemotherapy does not increase the risk of ORN.

The initiating injury resulting in ORN is frequently the extraction of a tooth from an irradiated mandible. For this reason, all teeth that might have to be removed should be extracted before starting radiation therapy. If clinical conditions permit, at least two weeks, and ideally three weeks, should be allowed for adequate healing between the extraction and the commencement of radiation therapy. Healthy teeth should be preserved. Dentures causing ulceration of the atrophic mucosa over the mandible can initiate ORN. Spontaneous ORN can also occur without any obvious injury to the irradiated mandible.

Traditional treatment of ORN with antibiotics and surgical debridement frequently fails with progressive involvement of the remaining mandible. The keystone of the treatment of ORN is the provision of adequate tissue oxygenation in the damaged bone. This is best done by using hyperbaric oxygen therapy (HBO). Multiple treatments are required. Early stages of ORN without fracture or fistulae may be cured by HBO alone. More advanced cases, in addition to HBO, require sequestrectomy or partial mandibulectomy with eventual bone grafting.

In the event that dental extraction is required following radiation, meticulous surgical technique and antibiotic prophylaxis are necessary. In those patients felt to be at particularly high risk of developing ORN, preextraction HBO should be considered. An alternative to postirradiation extraction is endodontic therapy.

Complications in the Pediatric Population

Oral complications arising from the treatment of cancer in children have characteristics in common with those observed in adults. However, because children are actively growing and developing, cancer treatment creates additional long-term problems unique to the pediatric patient. As modern therapy results in increasingly improved survival in a variety of pediatric cancers, long-term sequelae of treatment are beginning to emerge.

Some reports indicate that the frequency of oral complications in pediatric patients may be higher than in adults. The nature and severity of these treatment sequelae depend on a number of factors: the type and location of the tumor, the age of the patient, the dose of radiotherapy, the aggressiveness of chemotherapy, the status of oral and dental health, and the level of dental care before, during, and after therapy.

Chronic problems involving target tissues are impaired growth and development of hard and soft tissues, which may result in orofacial asymmetry, xerostomia, dental caries, trismus, and a wide variety of dental abnormalities. The latter include delayed tooth eruption, altered dental root development with shortening and thinning of the roots, enamel opacities, enamel grooves and pits, small teeth, small crowns, and failure of tooth development and eruption. In teeth with underdeveloped roots secondary to cancer therapy, even minimal periodontal disease will result in early loss of teeth. In general, the principles in the preventive and active treatment of xerostomia, dental caries, and trismus in adults appear to be applicable to children. However, evaluation of the efficacy and long-term consequences of these various strategies has not yet been carried out on a large scale.

These children may have lifelong dental problems requiring periodontic, orthodontic, prosthodontic, or orthognathic procedures. Supervised, consistent oral care, meticulous hygiene, and a regular dental recall schedule (to uncover problems early and determine the need for dental intervention) are key to maintenance of dental health care in children cured of their cancer. In addition, the emotional and psychological consequences of orofacial deformities and oral dysfunction in these children deserve more attention as increasing numbers survive.

The potential for development of secondary malignancies in these survivors is a serious delayed sequela of successful cancer therapy. Although a majority of secondary malignancies reported in children consist of leukemia or lymphomas, soft tissue and bone sarcomas can occur in irradiated sites. The possibility of secondary malignancies arising in these children should heighten the clinician's awareness of this problem.

Providing education and information to the patient and family is essential for maximum treatment compliance. Direct involvement of the family is thought to result in improved adherence to treatment protocols, thereby enhancing the quality of the patient's life.

The therapeutic team should be multidisciplinary and sensitive to the patient's emotional and physical needs related to the illness. Patients traumatized by the loss of normal oral function, the presence of pain, nausea, and impairment of eating, and a life-threatening illness can become depressed. The following preventive measures should be undertaken by the therapeutic team: provide information to increase the patient's and family's understanding of the medical/oral condition, the treatment plan, and the consequences of treatment. Methods of educating the patient/family should be individualized based on the diagnosis and needs. Patience and positive reinforcement are important.

What Are the Directions for Future Research?

- Devise accurate, quantifiable, reproducible criteria for assessing and classifying oral complications of cancer therapy.
- Determine incidence and prevalence of oral complications related to different types of anticancer therapies and related risk factors.
- Study the mechanisms of cancer treatment injury to the hard and soft oral tissues at the molecular and cellular level and determine how these affect the oral environment.
- Delineate the role of latent HSV activation in the pathogenesis of mucositis due to radiation therapy and chemotherapy of solid tumors.
- Study the frequency, clinical significance, and mechanisms of development of acyclovir resistance by HSV.
- Develop radioprotective and chemoprotective agents.
- Define the role of biological response modifiers, for example, rhG-CSF, in the prevention of myelosuppression and the influence of these agents on oral tissues and oral complications.
- Define and further document through prospective studies the effectiveness of initiating current pretreatment oral care procedures on the incidence, severity, and extent of oral complications of cancer management.
- Develop more effective sialogogues and saliva substitutes and evaluate their effectiveness in preventing the complications of xerostomia.
- Determine the most effective strategies to ensure patient compliance with therapeutic regimens.
- Define the role of the family support unit in the diagnosis, prevention, and treatment of oral complications of cancer treatment.
- Conduct further studies of the role of the oral cavity as a source of systemic infection.
- Conduct controlled studies to determine and test optimal antifungal therapies.
- Define patient populations that will benefit from prophylactic antiviral therapy.
- Define the role for oral antimicrobials in the prevention of infection in neutropenic patients and the effect of such prophylaxis on oral and gastrointestinal flora.
- Devise controlled studies of chlorhexidine and other agents for the control of mucositis in specified patient populations.
- Determine whether oral markers can serve as a predictor of problems of other organs.
- Develop more precise protocols for use of hyperbaric oxygen.
- Study disorders of taste perception in patients undergoing cancer therapy.
- Determine the cost-effectiveness of preventive, diagnostic, and therapeutic management of oral complications.
- Study the effect of different topical fluoride preparations to determine the most effective forms and dosage schedules.

The panel believes that many research goals can be achieved through coordination of committed members of the dental, medical, and nursing professions already actively involved in clinical investigations. Through such cooperative efforts, patients enrolled in ongoing investigations could serve to answer these important questions.

Deep concern exists that appropriate dental care may not be available due to a significant lack of appropriate levels of third-party reimbursement. This is particularly true when dental treatment necessary as part of the overall cancer management is not reimbursed.

Conclusions and Recommendations

- All cancer patients should have an oral examination before initiation of cancer therapy.
- Treatment of preexisting or concomitant oral disease is essential in minimizing oral complications in all cancer patients.
- Prophylactic acyclovir is beneficial in selected patients to prevent herpes simplex virus reactivation.
- Precise diagnosis of mucosal lesions and specific treatment of fungal, viral, and bacterial infections are essential.
- Mucosal ulcerations should alert the cancer team to the risk of systemic infection.

- Currently, the best treatments for chronic xerostomia include regular use of topical flourides, attention to oral hygiene, and sialogogues.
- Osteoradionecrosis can be prevented. When present, it is best managed with hyperbaric oxygen along or with surgery.
- In the pediatric population, it is important to recognize the long-term consequences of radiation therapy that include the dental and development abnormalities and secondary malignancies.
- Studies of oral complications should be incorporated into ongoing and future cooperative clinical oncology group protocols.
- Disseminate information concerning oral complications of cancer therapies and develop strategies to assure adherence by health care providers with appropriate preventive measures.
- Develop and implement curricula relevant to oral complications of cancer therapy in schools of medicine, dentistry, dental hygiene, and nursing.
- Direct family involvement in patient care is encouraged for maximum treatment compliance.

The *Journal of the National Cancer Institute* will publish a monograph containing the manuscripts of the papers presented at the consensus conference.

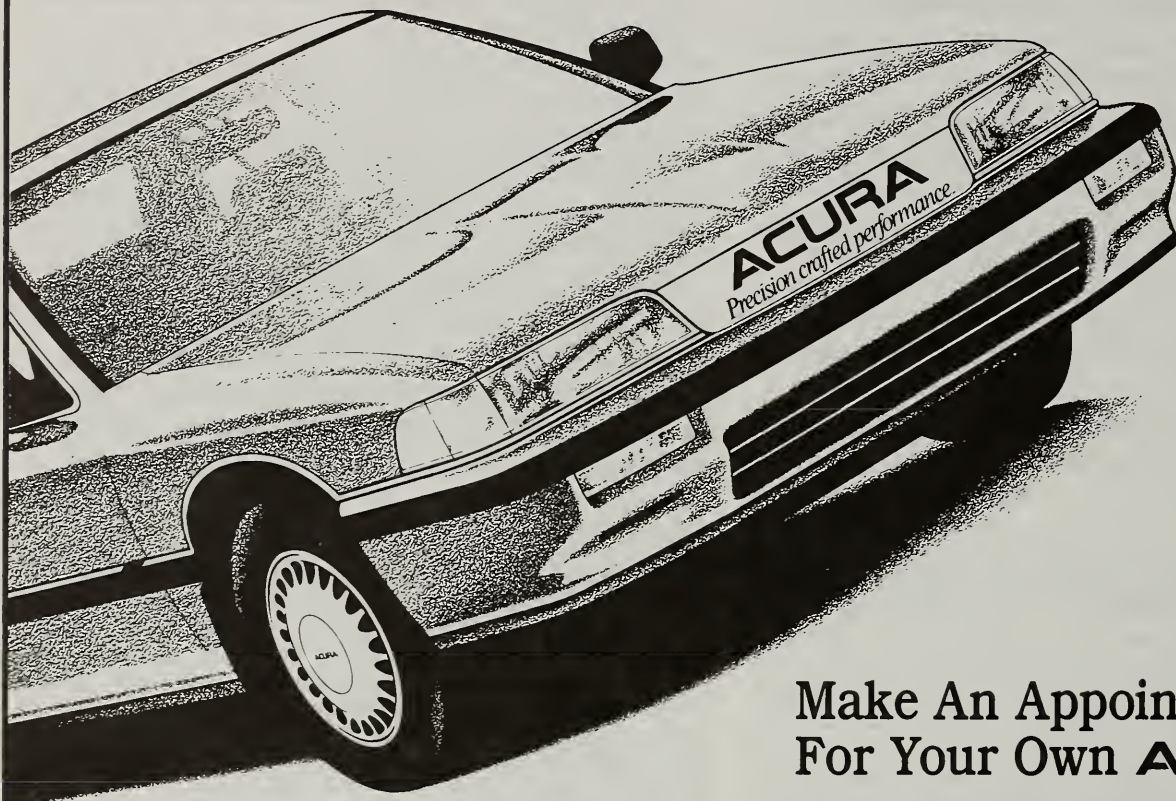
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Diclofenac

CLAIRE OGLE, R.Ph.

DICLOFENAC sodium (Voltaren® - Ciba-Geigy) is a nonsteroidal anti-inflammatory drug (NSAID) that was introduced to Japan in 1974 and has since been marketed in 120 countries around the world. Worldwide, diclofenac ranks as the top-selling NSAID, but has only recently been approved by the Food and Drug Administration for use in the United States.¹ It is indicated for acute and chronic treatment of the symptoms of rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis.

Pharmacology and Pharmacokinetics

Diclofenac belongs to a new class of NSAIDs. It is the sodium salt of a phenylacetic acid derivative.² All classes of NSAIDs act upon the cyclo-oxygenase pathway of the arachidonic acid cascade to inhibit the production of prostaglandins which are responsible for inflammatory reactions. Diclofenac, in addition to inhibiting the cyclo-oxygenase pathway, may also have two other mechanisms of action:

1. Inhibition of the lipo-oxygenase pathway of the arachidonic cascade which decreases production of proinflammatory leukotrienes.
2. Inhibition of arachidonic acid release coupled with stimulation of its re-uptake, both of which decrease the amount of arachidonic acid available to the cascade.¹

These two additional mechanisms are theoretically a potential advantage over other NSAIDs.

The tablet form of diclofenac is enteric coated and is almost completely absorbed. However, after undergoing first-pass metabolism, only 60% of the unchanged form of the drug reaches the systemic circulation.^{1,3} Peak plasma concentrations are reached within 1.5-2.5 hours after receiving the dose.³ The drug also distributes into synovial fluid, reaching peak concentrations about four hours after dosing with enteric-coated tablets.³ Despite

requiring a longer time to reach its peak concentration in synovial fluid, diclofenac persists longer in synovial fluid than in plasma. Its plasma elimination half-life is 1.2-1.8 hours, yet more than four hours after dosing, the synovial fluid concentration is still significantly greater than the plasma concentration.^{1,3} Diclofenac is greater than 99% serum-protein bound.¹ It is mostly metabolized in the liver resulting in active metabolites, followed by excretion of 65% of an oral dose into urine and 33% into feces.¹ The prolonged synovial concentrations of diclofenac coupled with its active metabolites allow it to be given twice a day despite the short plasma half-life.¹

Clinical Efficacy Trials

Because diclofenac has been available for such a long period of time in other countries, numerous and extensive clinical studies have been performed. Many of these trials are comparative studies with other NSAIDs. Zuckner evaluated the use of diclofenac in the treatment of rheumatoid arthritis, the most debilitating of the rheumatic diseases, by reviewing selected international studies. In the earlier phase of these trials, a dose of 75mg was used daily but later the daily dose was increased to 150mg daily. Overall, diclofenac proved to be at least equal to other NSAIDs with regard to its efficacy as an anti-inflammatory and analgesic agent, and to be better tolerated than other NSAIDs.²

In a review by Ward, five prospective randomized, double-blind, controlled trials of diclofenac in osteoarthritis performed in the United States with placebo, aspirin, and naproxen were compared. In these trials discontinuation of therapy due to unsatisfactory therapeutic response occurred in only 11% of patients treated with diclofenac compared with 34% (placebo), 17% (naproxen), and 16% (aspirin).⁴

In another United States study, diclofenac was shown to be also effective in ankylosing spondylitis both short-term and throughout the duration of a 38-week long-term study.⁵

Adverse Reactions

The major adverse drug reactions of concern with diclofenac are similar in nature to those of other NSAIDs which include gastrointestinal irritation or bleeding, cen-

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tral nervous system effects (headache, drowsiness, vertigo, insomnia, agitation), and decreased renal function during therapy. Based on clinical trials in the United States with most patients receiving 150mg daily of diclofenac, the incidence of adverse reactions was lower with diclofenac than with other NSAIDs, except for naproxen administered at a low dose of 500mg daily.⁶ However, in a large United States open controlled trial, meaningful elevations of SGOT and/or SGPT occurred in about 4% of 3,700 patients treated for two to six months. The FDA has thus recommended that the first transaminase measurement should be made no later than eight weeks after the start of diclofenac therapy.³ Another study of fecal blood loss in patients taking either diclofenac 150mg daily, aspirin 3.0g daily, or naproxen 750mg daily for 21 days showed that both aspirin and naproxen resulted in a greater amount of fecal blood loss than did diclofenac.² Studies by McMahon and Cash revealed that diclofenac was slightly better tolerated than indomethacin and noted that the adverse effects that actually occurred with diclofenac were mainly gastrointestinal effects while indomethacin caused more central nervous system effects.¹⁰

Caldwell reviewed five other studies in which 40% of patients treated with diclofenac experienced side effects, but most of these were mild and the frequency of side effects was similar to or lower than with other NSAIDs.¹¹ These studies also suggested that renal and hematologic side effects were not clinically relevant, nor were transient elevations in serum glutamic-oxaloacetic transaminase levels. Also, the incidence of adverse effects noted with diclofenac was similar to that of ibuprofen but less than aspirin.¹¹

Drug Interactions

Diclofenac does not appear to affect the hepatic demethylation pathway nor does it appear to affect the serum protein binding of other drugs. Therefore, the protein-binding of warfarin, tolbutamide, and prednisolone are not significantly affected by diclofenac.³ However, concomitant use of aspirin results in altered protein binding of diclofenac and an increase in its biliary elimination.¹ Therefore, in practice, aspirin and diclofenac should not be used together because it is a "pharmacologically unsound" combination; the clinical affects of either drug are not enhanced, and the incidence of adverse effects may increase.³

Other potential interactions may occur with antacids, hydrochlorothiazide, lithium, digoxin, methotrexate, and triameterene. Antacids may delay absorption of diclofenac without altering the total amount of drug absorbed.³ The effect of hydrochlorothiazide as an antihypertensive in essential hypertension may be inhibited by diclofenac.³ Plasma lithium concentrations should be monitored since diclofenac has been shown to increase serum lithium levels by 26% due to a 23% decrease in lithium renal clearance.³ Increased serum levels of digoxin have also been reported with diclofenac but without symptoms of overdosage.³ Digoxin levels should be monitored and

signs of toxicity should be noted. As with other NSAIDs, diclofenac when administered with methotrexate can cause a fatal reaction. This is possibly a result of decreased renal elimination of methotrexate, although the exact mechanism is unknown.³ Despite only one report of acute renal failure in patients receiving diclofenac with triamterene, it is advised to use caution with this combination.³

Dosage and Administration

In the treatment of rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis the recommended dosage ranges are 100-200mg/day, 100-150mg/day and 100-125mg/day respectively. Patients should be maintained on the lowest dosage of diclofenac that achieves satisfactory therapeutic response.

Cost Comparison

Usual Dosage in RA & OA	Cost/Day at Hartford Hospital
Diclofenac (Voltaren®) 100-200 mg/day	\$1.12 - \$ 2.24
Ibuprofen (Motrin®) 1.2-3.2g/day	\$0.15 - \$0.48
Piroxicam (Feldene®) 20mg/day	\$1.30
Sulindac (Clinoril®) 300-400mg/day	\$1.24 - \$1.57
Naproxen (Naprosyn®) 500-1000mg/day	\$0.94 - \$1.88
Diflunisal (Dolobid®) 500-1000mg/day	\$0.59 - \$1.18

Summary

Diclofenac is the newest NSAID to be introduced to the United States. Extensive worldwide clinical studies with diclofenac have demonstrated its efficacy in the treatment of rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis. Its overall safety and efficacy is comparable to other available NSAIDs. The potential advantage of diclofenac is its short serum half-life but long synovial fluid concentration which enables twice daily dosing.

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When Do Physician Recruitment Arrangements Affect a Hospital's Tax-Exempt Status?

LINDA M. WILDER-CURTIS, ESQ. AND ELLIOTT B. POLLACK, LL.B.

ABSTRACT—Physician recruitment arrangements by hospitals are becoming increasingly popular in today's competitive health care environment. A physician in private practice may seek the hospital's assistance in recruiting a new physician. This article highlights some of the issues which may affect a tax-exempt hospital's status and, therefore, will dictate some of the terms of those recruitment packages.

TO recruit physicians to practice in its service area, a tax-exempt hospital may use financial incentives such as guaranteed minimum salaries, relocation allowances, reduced rent or free office space, below market loans, malpractice insurance, equity ownership in medical office buildings, and one-time recruitment bonuses. If successful, such incentives produce beneficial results for both the hospital and the physician. However, an important but often overlooked issue is the possible affect of such strategies on the hospital's tax exempt status.¹

A hospital qualifies for tax-exempt status under Section 501(c)(3) of the Internal Revenue Code (IRC)² by satisfying four basic requirements. The hospital:

- must be organized and operated exclusively for charitable purposes;
- must be operated to serve public purposes rather than private interests (prohibition against *private benefit*);³
- may not engage in more than insubstantial amounts of lobbying; and,
- may not allow any part of its net earnings to benefit any private shareholder or individual (prohibition against *private inurement*).⁴

By attracting needed physicians to its service area, a hospital satisfies its charitable obligation to promote the health of the community. However, if the physician recruitment contract violates IRC prohibitions on private benefit or private inurement, the tax-exempt status of the hospital may be jeopardized.

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The Prohibition Against Private Benefit

A hospital will not qualify for tax-exempt status unless it serves the public interest and does not serve a private interest other than "incidentally." Where there is no cost or loss to the hospital, it is generally sufficient to show that a particular business transaction serves a public interest and furthers the exempt purpose. However, where there is a net cost or a loss to the hospital, the private benefit must be shown to be *both* qualitatively and quantitatively incidental.

The benefit will be *qualitatively* incidental if it cannot be achieved without necessarily benefitting certain private individuals, eg, the incentive was the *only* way to recruit the physician. The benefit will be *quantitatively* incidental if the value of the direct and indirect benefits to the hospital equals or exceeds the cost of the benefits received by the physician.

The Prohibition Against Private Inurement

Previously, only those individuals who controlled a hospital, eg, "insiders" such as directors, trustees, or officers, were considered to have a sufficient "private interest" in the activities of the hospital to be subject to this prohibition. However, in General Counsel Memorandum (G.C.M.) 39498,⁵ issued 24 April 1986, the Internal Revenue Service (IRS) took a very different position.

Although declining to rule conclusively on the issue in advance, the IRS noted that recruitment agreements *could* result in the physician's private interests being served other than incidentally, thus violating both the prohibition against private benefit and private inurement. The resulting violation could provide a basis for revocation of the hospital's tax exemption.⁶

In G.C.M. 39498, a rural tax-exempt hospital had guaranteed recruited physicians a subsidized annual in-

¹This article does not address other issues such as Medicare/Medicaid fraud and abuse, corporate practice of medicine, fee-splitting and professional medical malpractice which also may be raised by recruitment programs.

²I.R.C. §501(c)(3) (1986). Any references to the IRC are to the Internal Revenue Code of 1986, as amended.

³Treas. Reg. §1.501(c)(3)-1(d)(1)(ii).

⁴Treas. Reg. §1.501(c)(3)-1(c)(2) and §1.501(a)-1(c).

⁵Gen. Couns. Mem. 39498 (April 24, 1986).

⁶*Id.*

come for a two-year period with no obligation to repay the subsidy except out of income earned during the period in excess of the guaranteed annual minimum income. In exchange, the physician was required to provide services for the hospital including training and emergency room duties. The amount of the stipend was established by the hospital based upon the physician's qualifications and the hospital's needs.

The IRS found that such recruited physicians maintained a "close professional working relationship with the [exempt] hospital" and, therefore, were persons with a "personal and private interest" in the activities of the hospital subject to the prohibition against private inurement.

While the IRS conceded that a hospital "must offer incentives or inducements to attract qualified physicians needed in a particular area of specialization," if the hospital's tax-exempt status is to be preserved, the incentive plus the hospital-paid compensation, if any, must be "reasonable" compensation for the services rendered. Factors the IRS considers in determining whether compensation is reasonable include the reluctance of the physician to relocate, the competitive recruitment efforts of other hospitals, and the discernible direct relationship between the subsidy amount and the value of the physician to the hospital.

The IRS identified several major concerns with the recruitment plan including:

- the method of determining that the subsidy had no relationship to the value of the physician's services to the hospital;
- the program had no ceiling on the total amount of compensation (other than the guaranteed total annual minimum income);
- the absence of any requirement that the physician provide further services after the contract period; and,
- the lack of predictability in the amount of the subsidy.

G.C.M. 39498 has been criticized for adopting a reasonable compensation approach which presumes that hospital-physician relationships are similar to employer-employee relationships. In a physician recruitment program, however, the amount of the hospital's guarantee depends on both tangible and intangible factors, including the geographic location, the physician's specialty, the hospital's needs, and the parties' relative bargaining power. The IRS also appears to have expanded greatly the definition of "private shareholder or individual" from a person in control of the organization, eg, trustee, director, or officer, to include a newly recruited physician. Finally, it would appear that each physician recruitment agreement must be analyzed to determine whether an equivalent amount of benefit will flow to the hospital.

Conclusion

Based upon G.C.M. 39498, a hospital should:

- examine the entire compensation package from the prospective of both the prohibitions against private inurement and against private benefit;
- consider a one-time recruitment bonus, as discussed in G.C.M. 39498, the amount of which is determined by reference to the value assigned to recruiting the physician to the hospital's service area rather than to the services to be rendered;
- be aware that a recruited physician may be subject to reasonable compensation requirements;
- demonstrate reasonableness of the terms by arms length negotiations between unrelated parties and a realistic ceiling on the subsidy;
- have the hospital recover from the physician all funds advanced plus a reasonable rate of return;
- designate specific objectives for each recruitment;
- be prepared to document the need for such arrangement and the direct and indirect benefits to the hospital compared to the potential cost to the hospital.

CMIC Celebrates Fifth Anniversary

BEATRICE C. HOLT, CPCU

ON 1 October 1989 the Connecticut Medical Insurance Company celebrated its fifth anniversary. Established by the Connecticut State Medical Society in 1984, CMIC has grown from a fledgling insurance company to the principle source of professional liability insurance for physicians in Connecticut.

With its recent announcement of rate decreases for the 1990 policy year, CMIC is fulfilling its initial promise to Connecticut physicians:

- to provide the best claims, risk management, and policyholder services possible,
- to receive the benefit of all investment income, and
- to reduce operating expenses.

These efforts have resulted in a steady decrease in annual premium adjustments. The factors that have influenced this trend are principally:

- reduction in the number of claims reported (frequency)
- restructuring of CMIC's reinsurance
- lower administrative expenses
- higher investment income

On the occasion of CMIC's fifth anniversary we have undertaken a review of membership benefits. Many of the benefits are a result of the completion of five years of operation.

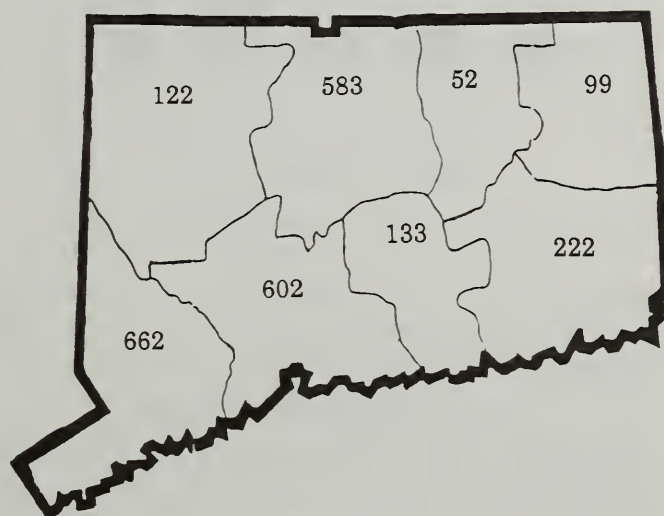
Membership Growth Realized

CMIC has experienced steady growth in membership over the past five years. Beginning in 1984 with 925 members CMIC currently insures 2,475 physicians. This represents more than 55% of potential members. One-half of CMIC's members have reached the "mature" or fifth claims-made step. By 1991 80% of membership will have reached this mature claims-made status.

With 65% of CMIC's membership under the age of 50, the Company has an excellent long term member base and plans a continued steady increase in membership.

BEATRICE C. HOLT is the Vice President, Risk Management and Marketing for the Connecticut Medical Insurance Company (CMIC), Wallingford.

CMIC MEMBERSHIP BY COUNTY



Total Membership - 2,475

As of August 1, 1989

Stabilization of Premium Achieved

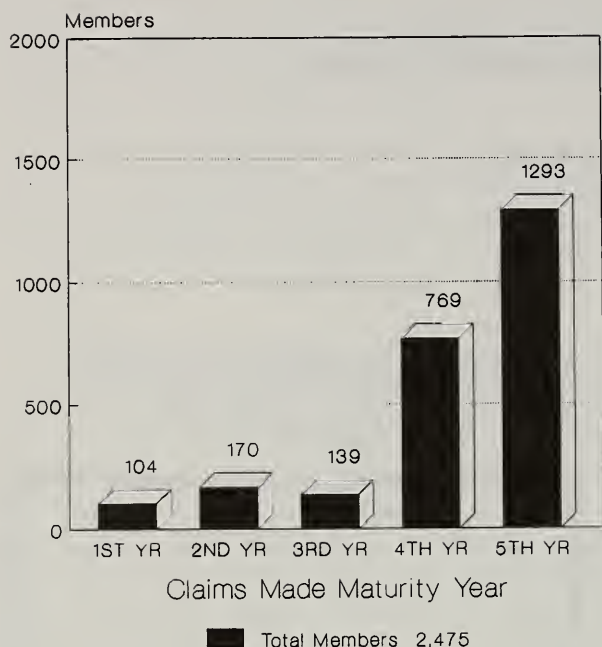
Achieving mature claims-made status results in the elimination of the claims-made step increases and a stabilization of premiums. The annual rate adjustment becomes the only factor to affect a change in premium. For 1990 the announced rate decreases will benefit every CMIC member. The amount of benefit will depend on each physician's claims-made year and limits of liability. (See graph, "Membership by maturity year.")

Responsive Risk Management Programs Introduced

Since 1986 CMIC has introduced many innovative risk management education programs. These programs have allowed members to earn premium credit and CME credits while learning to enhance their professional relationships.

A Defendant Support Program was introduced in 1988 for physician defendants and their spouses. The

CMIC MEMBERSHIP BY MATURITY YEAR



As of January 1, 1990

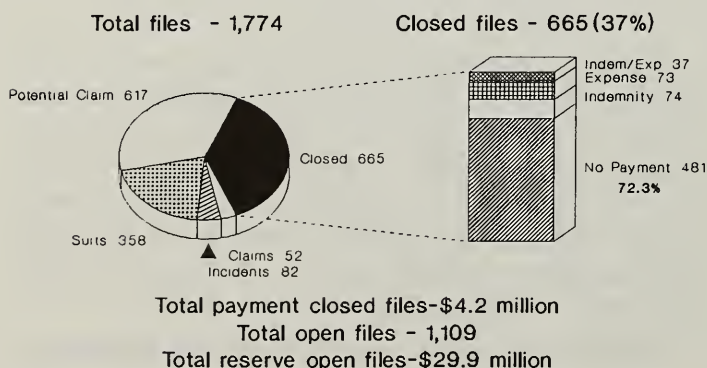
program explores the psychological impact that becoming a defendant has on the physician and reviews the process of a lawsuit from initiation to resolution.

Claims Experience as Predicted

A five year review of claims experience reveals that 1,774 files have been opened on cases reported to CMIC. Of the 665 files closed, 481 (72%) have been closed with no payment. On the remaining closed files \$4.2 million had been paid as of June 30, 1989.

CMIC CLAIMS

October 1, 1984 - June 30, 1989



In 1984 projections of claims reserves and payouts were made for the 1984-85 policy year. A look at CMIC's first policy year experience, almost five years after incep-

tion, begins to validate the premium and payout assumptions made when CMIC was established.

Full Retirement Benefits Available

Physicians age 60 or older who have been insured with CMIC for five consecutive years are now eligible for a free "tail" (extended reporting period endorsement). A credit program of 20% per year toward the purchase of a "tail" is available to members retiring at age 55 or older who are not eligible for the free "tail."

A recent preretirement benefit, waiver of the prior acts adjustment, became available to members under certain circumstances. This benefit can ease the financial considerations that previously accompanied a physician's decision to reduce risk classification or change from full time to part time practice prior to retirement.

Several hundred members are eligible to take full advantage of CMIC's retirement benefits now that the fifth year milestone has been reached.

Disability Benefits Enhanced

The following enhancements to the disability benefits have recently been approved by the CMIC Board of Directors.

Total Permanent Disability - If a member becomes totally and permanently disabled and therefore unable to perform the substantial and material duties of his/her medical specialty the following options are available:

- cancel the CMIC policy and receive a free "tail," or
- continue to practice on a modified basis and receive the benefit of a prior acts adjustment waiver.

Example: a surgeon who is disabled and unable to perform surgery could continue to practice by assisting in surgery only and maintain an office-based practice without the usual financial obligations of a prior acts adjustment. As an alternative, the surgeon may chose to retire from practice and receive a free "tail."

Temporary Disability - During a temporary disability or extended illness, i.e., coronary artery bypass surgery, a member may temporarily suspend his/her policy and pay a nominal monthly premium until returning to practice.

While subject to underwriting review, disability benefits are available to all members regardless of age or time with the Company.

Summary

CMIC has demonstrated a commitment to its physician members, and an ability to implement a premiere insurance program aimed at addressing the needs of CSMS physicians. It is evident that CMIC members are realizing the benefits offered by a physician-owned and physician-directed company. The foresight of the CSMS leadership in 1984 has allowed Connecticut physicians to gain control over their professional liability insurance.

Editorial

Animals and Human Life

Those of us old enough to have read newspapers in 1944 still remember the excitement that surrounded the announcement of the first "blue-baby" operation in November of that year. As the result of experimental surgery on about 200 anesthetized dogs, researchers at Johns Hopkins Hospital had perfected an operation to treat a previously lethal heart disease of children. The procedure was a giant step toward the modern era of cardiac surgery that has since transformed the lives of millions of patients and their families.

As astonishing as it may seem, there were organized protests against the continuation of the life-saving research. A rapid series of dramatic advances by American medical scientists had aroused the ire of a strident group of Baltimore animal-rights advocates, or antivivisectionists. Over the next few years, harassment of laboratory personnel and animal vendors caused increasing difficulties in obtaining stray or pound dogs. The antivivisectionists demanded nothing less than the prohibition of all animal research.

Then, as now, Baltimore was one of America's great centers of medical progress. Faced with the potential tragedy of halting vital work, the Johns Hopkins leadership brought the problem to the Baltimore City Council in 1949. Although many prominent people came to the public hearings to speak out in favor of animal experimentation, the highlight of the deliberations was the dramatic testimony of the operation's coinventor, Dr. Helen Taussig, the world's first pediatric cardiologist.

This extraordinary woman, as well known for her compassion as for her brilliance, did not enter the hearing room alone. She brought with her a joyous parade of healthy, smiling, former blue babies for whom animal research had provided the gift of life. Many of the children brought along their own pet dogs. When an antivivisection bill came to a referendum at the next municipal election, the people of Baltimore defeated it by a majority of more than four to one.

Forty years have passed, and the American public is once again being bombarded with self-righteous protests against medical progress. Once again, the obstructionists are few in number but loud in destructive clamor; once again their weapons are half-truths and a disordered perception of morality and society's values.

The dangerous campaign being waged by the animal-rights activists is not a struggle against medical science alone, it is a struggle against humanity.

The ultimate question that Americans must answer was framed by Harvard physiologist Walter B. Cannon as long ago as 1908, during the first of the several periodic revolts against common sense that have imperiled the welfare of the sick since that time: "Shall men suffer and die to save the lives of the experimental animal, or shall the experimental animals die to mitigate pain and wide calamity among men?"

The antivivisectionists would have us believe that animal research is no longer necessary because it can now be replaced by artificial constructs and computer-generated methodology. They insist that this is so, even though the better-informed among them must be aware that the National Research Council has spent three years and \$315,000 studying whether such a claim has any hope of becoming a reality in the foreseeable future. The council's recently released report comes to a succinct conclusion: "Animal experiments are still critically important to further improvements in medicine and biomedical science."

The report describes contributions that such experiments have made to the treatment of patients with polio, AIDS, cardiovascular and kidney diseases and psychological illnesses, as well as those who require surgery of any kind, particularly organ transplantation.

Friends of scientific research were disappointed that the study could not come up with evidence that might indicate at least some potential for an early decrease in the need for animals. It is well known, antivivisectionists to the contrary, that most scientists avoid the use of animals whenever possible, if for no other reason than the pragmatic one that they are expensive to acquire and maintain.

The many splinter groups of antivivisectionists go by names as seemingly innocuous as the Animal Welfare Institute to appellations that leave no doubt about disruptive intentions, such as the Animal Liberation Front. Regardless of name or avowed motivation, virtually all the rights groups exist to stop all research on animals, whether in one direct legislative action or in a series of progressive limitations that eventually will make such studies prohibitively expensive.

All of this is undertaken in the name of some disordered concept of mercy and the purported equality of all God's creatures. Deliberately ignored are the great gifts that have been made and will continue to be made to the health of human beings (and of domestic and farm animals) by research that involves animals. Most misguided of all, the activists mistake the Judeo-Christian ethic that is the foundation of Western morality. In that ethic, there is no higher good than the value we place on human life.

Sherwin B. Nuland, M.D.

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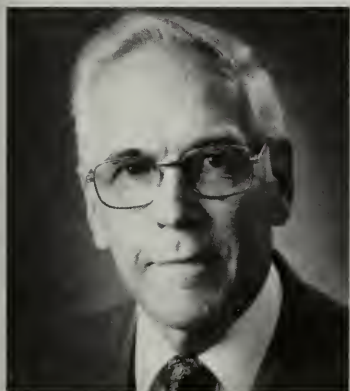
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JCAHO



The Joint Commission on the Accreditation of Healthcare Organizations, formerly known as the Joint Commission on the Accreditation of Hospitals, currently is reviewing many Connecticut hospitals and their medical staffs. Those of you familiar with this survey process know that it is thorough and detailed. The surprise for you will be the much increased emphasis on the quality of patient care, how well you document your part in that care, and who monitors and evaluates the care you give. No longer does the Joint Commission seek to determine what you and your hospital can do, but rather, what you are doing. The focus now is on patient care outcome both on the part of the hospital and the individual physicians on its staff.

The JCAHO is an independent, nonprofit organization governed by a 22 member Board of Commissioners — seven appointed by the American Medical Association, seven by the American Hospital Association, three by the American College of Physicians, three by the American College of Surgeons, one by the American Dental Association, and one board-appointed private citizen. Dennis O'Leary, M.D., serves as president. After policy is established by the board, Dr. O'Leary and his staff in Chicago, working with Advisory Committees, develop the detailed requirements for the survey. Physicians, nurses, and administrators are recruited, trained, and assigned in teams of three to conduct the surveys. Although it is voluntary, the great majority of hospitals and many other health care entities seek accreditation in order to receive Medicare payments and, in many states, institutional licensure.

Since its formation in 1951, the JCAHO has had as its major concern quality health care. Minimum standards of care were established at first. Later an optimal achievable level of care was set as a criterion. During the 1970s standards were again raised and retrospective medical audits introduced. For the past 10 years better definition and measurement of the quality of patient care has been the goal. This, of course, means closer scrutiny of each hospital and each physician's in-hospital activities. It is no news to any of you that many others are looking at what you do — HCFA, CPRO, HMOs, insurance companies, etc. — although the goal is not the same.

The physician member of the JCAHO survey team reviews all aspects of the medical staff organization and function but **Quality Assurance** is the focus. Does the hospital have a written quality assurance plan? Does it have a quality assurance committee including physicians? Does the quality assurance committee report regularly to the board of directors? Do the departments discuss quality assurance at their meetings and record this in minutes sent to the quality assurance committee? More significantly, as far as physicians are concerned, do the clinical departments conduct studies, retrospectively in response to an identified patient care problem, or prospectively to measure the quality of patient care? What action is taken if a physician appears to be giving substandard care as determined by one of these studies and where is it recorded? Monitor and evaluate, described in the two preceding sentences, are at the heart of the quality assurance program. Departments are expected to conduct such studies. Physicians are required to have in their individual credentials folders in the staff office rather complete information including biographical data, licensure, delineation of privileges, meeting and committee attendance, complications and deaths, and drug and blood usage for evaluation by the department director.

The mission of the JCAHO is evaluation, education, and consultation with the goal of quality patient care. As physicians we have the same goal. Our voluntary participation with them, burdensome as it may be, benefits both patients and physicians.

Roger S. Beck, M.D.
President

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Pierre Louis and His Numerical Method

ROBERT U. MASSEY, M.D.

Pierre-Charles-Alexandre Louis (1787-1872) is little known outside medical historical circles; only one of my internist friends knew about his bloodletting study in patients with pneumonia, and a surgeon proudly remembered the angle of Louis, but that turned out to be a different Louis (Antoine). P.C.A. Louis belongs to the time before that burst of biomedical science in the second half of the 19th century, the time just after Bichat, Laennec, and Bayle in France, and nearly contemporary with Graves, Stokes, and Bright in Great Britain. Most of us recall names in biology and medicine back through our grandfathers' and even great-grandfathers' generations, but then the mists close in obscuring our vision. The early decades of the 19th century, separated from the Enlightenment by the two revolutions, seem like the early morning hours of our modern world. But this is no place for a historical analysis of the social, cultural, political, scientific, and technical forces that shaped the remarkable European and American 19th century. Historians will be doing that for years to come.

Pierre Louis can claim special honor for his "numerical method" and his requirement for rigorous observation. By impartially collecting facts, carefully recording and analyzing his data using numbers, and following his motto, "Ars medica tota in observationibus," Louis established the foundations of clinical medicine on the firm ground of statistical method. For nearly seven years he lived at la Charité (1820-27), collecting and analyzing his thousands of observations on typhoid, tuberculosis, yellow fever, and diphtheria. Applying his method to 78 cases of pneumonia, as well as to erysipelas, tonsillitis, and pleurisy, he challenged the efficacy of bloodletting—the mainstay of medical treatment for more than 2,300 years—by showing that it failed to arrest pneumonia at its onset and had little effect on its course.

Louis was the teacher of many Americans, including among others Oliver Wendall Holmes, George Cheyne Shattuck, and H. I. Bowditch. One rainy day in October 1905 William Osler with some American colleagues placed a wreath of autumn leaves on his almost forgotten tomb in the cemetery in Montparnasse to mark "...Louis's

life which has no parallel in the profession;..." and to reaffirm "...his special claims to remembrance—not so much his attempt to introduce mathematical accuracy into the study of disease, as his higher claim to have created the American school of clinical medicine through his pupils."¹

For us Louis's story is a reminder that important clinical questions will be answered only by meticulous, impartial clinical observation, driven by a lively scepticism about most forms of accepted therapy. I recall when we began to doubt the efficacy of dicumerol in the management of myocardial infarction; a cardiologist, beginning to lose his faith, remarked that no one would have the guts to do a serious clinical study. And there are other fashions that have or will follow the way of bloodletting: the Sippy regimen, tonsillectomy, radical mastectomy; everyone has his list of the controversies. How many present orthodoxies, so secure and safe, will fall before 21st century Louises? The profession had invested heavily in bloodletting; just before Louis, Francois Broussais, the dominant figure in Parisian medicine, was advocating heroic bleeding or leeching for almost all diseases; he was a formidable adversary.

We invest much of ourselves in our orthodoxies, and they are defended by powerful champions, not only in medicine, but among the stockholders and managers of pharmaceutical companies and the investigators whom they support, and among patients who dislike having their habits questioned or faith shaken. To confess that we have been wrong, led on by the fashion of the day, and to explain why, is not easy and is often poorly received.

The recent studies of variations in medical treatment from one place to another have been of intense interest to those whose only goal is to contain costs. These studies ought to be of greater interest to clinicians for they are a kind of superficial updating of Louis's *Researches on the Effects of Bloodletting in Some Inflammatory Diseases*.² They ask unambiguous questions that cry out for honest answers.

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Life After *Webster*: The More Things Change...

JOSEPH M. HEALEY, J.D.

IN the almost 17 years since the United States Supreme Court established boundaries for state regulation of abortion in the cases of *Roe v Wade*¹ and *Doe v Bolton*,² the issues at the center of our continuing societal policy debate have remained essentially the same: whether there are limits to governmental regulation of reproductive decisions (including abortion); if such limits exist, in what source(s) they are grounded; and how such limits may be implemented to identify and protect the rights of affected parties. The recent decision in *Webster v Reproductive Services Inc.*³ represents the latest chapter in this ongoing saga and leaves us, once again, with more questions unanswered than answered.

Last month's column described the continuing lack of consensus among the Justices. It is noteworthy that only one section of the *Webster* decision (II C) attracted the unanimous agreement of the Justices. This section dealt with a technical issue not essential to addressing the primary issues raised in the case. There was uniform agreement that this part of the lower court decision should be overturned. Otherwise, there was sharp division among the Justices.

Despite strong words from Justice Scalia, the framework for regulating abortion articulated in the Court's previous decisions was not overruled. Shaping the Court's handling of the case was a core majority of five Justices (Rehnquist, White, O'Connor, Scalia, and Kennedy) who held that (1) it was not necessary to pass on the constitutionality of the Missouri abortion statute's preamble which found that life begins at conception and that unborn children have legally protectable interests; and (2) that provisions of the Missouri statute which imposed restrictions on the use of public facilities for the performance or assistance of nontherapeutic abortions were constitutionally valid. The greatest disagreement

arose over the provisions of this section of the statute:

Before a physician performs an abortion on a woman he has reason to believe is carrying an unborn child of twenty or more weeks gestational age, the physician shall first determine if the unborn child is viable by using and exercising that degree of care, skill, and proficiency commonly exercised by the ordinarily skillful, careful, and prudent physician engaged in similar practice under the same or similar conditions. In making this determination of viability, the physician shall perform or cause to be performed such medical examinations and tests as are necessary to make a finding of the gestational age, weight, and lung maturity of the unborn child and shall enter such findings and determination of viability in the medical record of the mother.⁴

All five of the opinions in the case dealt with these provisions. Three of the opinions representing five of the Justices concluded that this section is constitutional and refused to hold it unconstitutional. Two of the opinions representing three of the Justices would hold the section unconstitutional. By a plurality of five to four, the provision was held to be constitutional.

This description of the *Webster* case underscores the bitter lack of consensus which exists about the abortion issue in the United States. The emerging majority would have this absence of consensus resolved through the political process, viewing reproductive rights as the product of legislative activity rather than as grounded in the United States Constitution. It remains to be seen whether such deeply held, deeply divisive issues can be any better addressed by the legislative branch of government than they have been by the judicial branch.

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JOSEPH M. HEALEY, J.D., Associate Professor, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington, CT.

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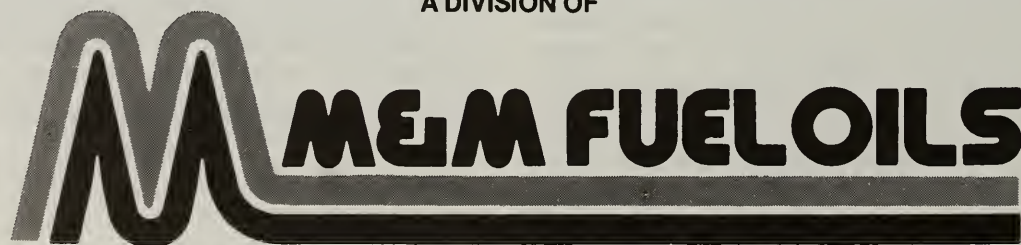
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50 Years Ago
From the *Journal of the Connecticut State Medical Society*
October 1939

Valedictory*

CREIGHTON BARKER, M.D.
New Haven, CT

On April 27, 1922, this Association honored me by electing me its Clerk, and for exactly seventeen years to a day, I have served you as your Clerk, Vice President and President. It has been a unique and valuable experience. In more than 150 years of the Association's life no one has served continuously for so long a period, and I shall always look back upon it with pride and affection. It has contributed a great deal to my life, and I am grateful. To all of you with whom it has been my privilege to work as Officers and on Committees, I want to express my appreciation and thanks for your unselfish cooperation and thoughtful judgment that has contributed so much to the progress and prosperity of the Association. Many who gave me the most guidance and instruction are no longer here, the debt that I owe to Doctor Carmalt, John Lane and Frank Wheeler for clear thinking and honest help can never be repaid, and the fine pleasure that I had in intimate association with Walter Barber, Louis Gompertz and Harry Anderson is quite beyond value. My contribution in return for all this has been small but I have served with good intent. Today, five minutes ago, it came to a technical end, but I have no sadness, I am pleased to step aside and welcome my steadfast friend, Cole Gibson, as my successor. You have chosen well, he will wisely administer your affairs.

It may be that when the final scroll of history is unrolled, these seventeen years will span the greatest changes that medicine will record, the closing of an old epoch and the opening of a new. The science of medicine has made great progress during those years in the vast field of chemistry in relation to disease, in the entirely new knowledge of the vitamin elements in diet; in a practically workable understanding of the functions of the endocrine glands; in the treatment of disorders of metabolism; in the almost uncanny results of research in

specific chemotherapy and in the development of new skills in neuro and thoracic surgery. It has been a time of extraordinary achievement, new in concept, new in design; many ancient and inadequate methods have been discarded, and new ones sought and found. While all this has been going on in medical science, a part of medicine has remained static. It is a rather intangible part to which we have heretofore given little thought, and is not easy to define simply. Perhaps the "availability" of medicine is the best way to put it. The science and methods of medicine have gone ahead so fast that devices for the useful distribution of them have not kept pace. The reasons for this are numerous and complicated, partly economic, partly social and partly our own fault. And they are so closely interwoven that although they may be independent they are practically inseparable.

By a strange coincidence this Association was meeting in Waterbury on that fateful October day in 1929, when the security and commodity markets collapsed. Not many members were courageous enough to leave their broker's offices, and those who did come to the meeting were more interested in the Wall Street dispatches than in the program. At the time not one of us realized the far reaching influence the hectic happenings of that Thursday and the events that led up to them, would have on medical practice ten years hence, but surely the professional lives of us all have been affected by disrupted economics.

Jolted by economic catastrophe society has become disordered, political parties have new bases for alignment, labor has become increasingly powerful, capital enterprise has been looked upon with disfavor, and medicine has ceased to be an independent priesthood, a law unto itself. Perhaps I draw too simple an analogy, when I see that the people are coming to look upon medical care as a public utility, like electric power, needed by everyone and necessarily available to meet that need. In all logic it

*Address of the retiring President, New Haven County Medical Association, April 27th 1939.

is not an unreasonable point of view, but we have not been quite willing to accept it. We are reluctant to forsake some of our old traditions, and somewhat remiss in our efforts to mold public opinion. A rather one sided picture has been presented to the public, and the other phases of the problem will remain unexplained unless medicine itself undertakes the task. Changes in the distribution of medical care are going on, and I believe others are bound to come. This will inevitably lead, as it has already led, to increased interest in medical practice on the part of the people, and increased influence and authority over medical practice from Government, which is the people's agent.

If the best interests of our profession are to be served during these times of confusing change, medical associations such as ours can no longer remain quiescent laissez-faire organizations with their future behind them. Our problems are no longer wholly within ourselves. American medicine has reached the stage where it is playing a vital role in the nation's economy. We have a public and social responsibility that must be met, not to see those responsibilities reflects upon our intelligence, to shrink them will surely bring us discredit.

No one is more reluctant than I to advocate that medicine go into public politics, but the fact is that politics have come into medicine, and wisdom points

that we should meet the situation fairly and with the honest strength that is surely ours to use.

There will be some among you who will feel that the views I have expressed in this brief valedictory are too pessimistic, you may call them radical. It is in my peaceful heart to agree with the most conservative of you, but alas! I cannot delude myself. The relatively calm order of medical practice that prevailed that fine autumn day seventeen years ago when I first became your Clerk, has gone, and no amount of pious hope or wishful thinking on your part or mine will bring it back. In the new scene are things that are neither familiar nor sentimental objects, but I am confident we are intelligent enough and ambitious enough to shape the new order for mutual good.

Connecticut is still the land of steady habits, and the best of these is the habit of slow and careful thought. This State is our home, for some a home by birth and inheritance, for others from distant lands a home of happy adoption; but in all of us is an integrity of character that makes us unselfishly willing to serve our fellow man, and a quality of mind capable of facing our problems and soundly and fearlessly arriving at their solution. This Association has opportunities for service that it must meet if medicine is to go on in the self reliant pride that is our honest heritage.

CALL FOR PAPERS

Members of the Connecticut State Medical Society reading papers before other organizations are requested to submit their papers to the JOURNAL for consideration by the Board of Editors for publication. Authors preparing manuscripts for submission to *Connecticut Medicine* should consult **INFORMATION FOR AUTHORS**. This material may be obtained from the *Journal* office. Adherence to the instructions will prevent delays both in acceptance and in publication.

Please send them to: Robert U. Massey, M.D., Editor
 Connecticut Medicine
 160 St. Ronan Street
 New Haven, Connecticut 06511

AROUND THE STATE

Connecticut Chapter ACP Meeting

The American College of Physicians, Connecticut Chapter held its annual scientific meeting at the Ramada Renaissance Hotel in Southbury on 6 October, and followed this with an associates' meeting on 7 October. The departments of medicine at St. Mary's Hospital and Waterbury Hospital were cohosts, and **Drs. David Podell** and **Majid Sadigh** were co-chairmen. The welcome was given by **Dr. George F. Thornton**, ACP Governor, Connecticut Chapter, and **Dr. James P. Nolan**, professor and chairman of the department of medicine at SUNY-Buffalo School of Medicine, and Regent of the College presented a talk, "The ACP—Position for Leadership in the 90s."

Laureate Awards were presented to **Dr. Thomas T. Amatruda**, Waterbury; **Dr. Philip Morgenstern**, Farmington; and **Dr. James Duncan Kenney**, New Haven.

Programs and Courses

The University of Connecticut School of Medicine, The University of Massachusetts Medical Center, and the New England AIDS Education and Training Center are sponsoring a project entitled: **AIDS/HIV Infection: Management in the Primary Care Setting** to be held at six locations between 30 November and 27 April. **Dr. Harry Katz-Pollak**, assistant professor of medicine, University of Connecticut School of Medicine, will be joined by **Marie Hebert-Begley, R.N.**, and **Tricia McCooey, M.S.W.**, in presenting these one-day sessions. The dates and locations are:

1. 30 November 1989 (Thursday)
Uncas on Thames Hospital, Norwich
2. 8 December 1989 (Friday)
Johnson Memorial Hospital, Stafford Springs
3. 25 January 1990 (Thursday)
Charlotte Hungerford Hospital, Torrington
4. 23 February 1990 (Friday)
The University of Hartford,
Konover Campus Center, West Hartford
5. 30 March 1990 (Friday)
Day Kimball Hospital, Putnam
6. 27 April 1990 (Friday)
Manchester Memorial Hospital Manchester

For further information, call Cecile J. Volpi, Director, Office of Continuing Education, at (203) 679-3340.

The Seventh Annual Ella T. Grasso Memorial Conference sponsored by the Division of Gynecologic Oncology at Yale University School of Medicine, Yale Comprehensive Cancer Center, and the University of Connecticut School of Medicine will be held on Wednesday, 15 November 1989 at The Park Plaza, 155 Temple Street, New Haven. **Peter E. Schwartz, M.D.** is the Program Director.

For information call the Office of Postgraduate and Continuing Medical Education, 785-4578.

Letter to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

MORE ON THE OATH, THE ART, AND THE CARING

To the Editor: I enjoyed the essay by Dr. Maletz entitled, "The Oath, the Art, the Caring" in *Connecticut Medicine*, Volume 53, pages 431-432, July 1989. The oath of Hippocrates has always been a favorite, and I have enjoyed it in the original as a consequence of studying ancient Greek in college. There is a Physician's Prayer that is even more immediate, personal, gratifying, and inspiring, however, and that is the Prayer of Maimonides for the Physician. This medieval philosopher and physician produced a warmth, and a focus on the physician-patient relationship that have never been exceeded. Attached is a copy of one version of this Prayer. I hope that some readers of *Connecticut Medicine* will photocopy both the oath of Hippocrates from the essay by Maletz, and the Physician's Prayer of Maimonides, to retain always in their possession and in their hearts.

Physician's Prayer of Maimonides

Grant me an opportunity to improve and extend my training, since there is no limit to knowledge. Help me to correct and supplement my educational defects as the scope of science and the horizon widens every day. Give me courage to realize my daily mistakes so that tomorrow I shall be able to see and understand in a better light what I could not comprehend in the dim light of yesterday. Bless me with a spirit of devotion and self-sacrifice so that I can treat and heal Thy suffering servants and prevent disease and preserve health to the best of my ability and knowledge.

Grant that my patients have confidence in me and my art and follow my directions and counsel.

Oh grant that neither greed for gain nor thirst for fame nor vain ambition may interfere with my work.

May I see in the afflicted and the suffering only a fellow human being in need.

Unknown translator; quoted in Pappworth MH, **A Primer of Medicine**, fifth edition, London: Butterworths, 1984; 2.

Henry Schneiderman, M.D.,
Associate Professor of Medicine and Pathology
University of Connecticut School of Medicine
Farmington

From the Executive Director's Office

CALL

SEMI-ANNUAL MEETING OF THE HOUSE OF DELEGATES

The 1989 Semi-Annual Meeting of the House of Delegates will be held at the Ramada Inn, 201 Washington Avenue, North Haven. The meeting will commence at 12:30 P.M. on Wednesday, November 15, and will continue until all business has been concluded.

11:30 Registration and Luncheon

12:30 Call to Order

Roger S. Beck, M.D., President

Kenneth M. Robbins, M.D., Speaker

Marjorie G. Petro, M.D., Secretary

INTRODUCTION OF RESOLUTIONS

Article V, Section 12, Par. 3 of the Bylaws of the Society provides that:

Resolutions may be introduced by any Active, Life Member, Student Member or Postgraduate Physician Member of The Society, in compliance with the following provisions.

- a. *All resolutions, reports and similar items of business submitted in writing and received at the office of the Executive Director not later than thirty days before the date scheduled for that meeting shall be considered as regular business of the House of Delegates.*
- b. *Component county associations or the Student Member or Postgraduate Physician Member Associations whose meetings are held later than thirty-five days prior to the date of the House of Delegates shall be allowed five days after the close of such meeting in which to submit resolutions, reports, and similar items of business to the Executive Director's office and still have such material considered as regular business. In no event, however, may such resolutions, etc., be considered regular business if they are received later than fifteen days prior to the date of the meeting.*
- c. *Reports, recommendations, resolutions, or other new business may be presented to the House of Delegates by the Council of The Society at any time and shall be considered regular business.*
- d. *Any business which does not qualify as regular business in accordance with the foregoing provisions may be accepted for considerations by a majority vote of the delegates present and shall be referred at once by the Speaker to a reference committee. When business is introduced under the provisions of this paragraph the vote shall be taken without debate, except that the introducer shall be allowed not more than two minutes to explain why it should be considered as regular business.*

COUNCIL MEETING

Thursday, September 7, 1989

Attendance

Present in addition to the Chairman, Dr. Joseph C. Czarsty were Drs. Ahamed, Blum, Bobruff, Bonner, Catrini, Dardick, Eslami, Freedman, Hollister, Jr., Kamens, Keating, McDonnell, Orphanos, Petrie, Redmond, Robbins, Rose, Sadowski, Sosa, Wetstone, Zanker, and Zeppieri.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Sullivan, Ms. Ballou, Mr. Tomat (FCMA), Ms. Clark (HCMA), Mr. Freberg (NHCMA), Dr. Steven Thornquist (Delegate, Resident Physician Section), and Mrs. David Reed (President, Auxiliary).

Absent were: Drs. Beck, Chmieski, Fox, Kaufmann, Lesnik, Meridy, Parikh, Petro, Reyelt, Jr., Schwartz, Welch, and Zlotsky.

Approval of Minutes

It was VOTED to approve the minutes of July 26, 1989 as published and distributed. Dr. Czarsty discussed the issue of mailing individual copies of the Council minutes to the entire House of Delegates. He stated that due to the logistics of preparing Council minutes and having them approved, the minutes are published in the CSMS Journal at about the same time that individual copies are mailed to each delegate. It was reported

that, with the *Journal* available to all delegates, the practice of mailing minutes to delegates was redundant and an unnecessary expense. This was particularly true since a summary of all Council actions from the previous House of Delegates is included in the Handbook provided each delegate before each House of Delegates meeting. Following discussion, it was VOTED that sending copies of the minutes of the Council meetings to the entire House of Delegates be discontinued and that delegates be asked to refer to the *Journal* for the most recent minutes. Jerome Freedman, M.D., wished to be recorded as voting "no" on this question.

Reports on Related Organizations

CPRO: Dr. Kamens reported that CPRO activities were progressing very smoothly and that the third contract material was received with a request for a proposal, which will be addressed in the next 60 days. This contract will be for three years and the hope was expressed that CPRO be awarded it again.

Report of the President

In the absence of Dr. Beck, Dr. Czarsty reported that Dr. Beck wished him to report to the Council on the subject of many senior citizens having multiple prescriptions and the problem of interaction of these medications. Dr. Beck wished the Council to consider promot-

ing a campaign whereby CSMS would provide bags to senior citizens in which they could collect all their prescription medications and bring them to their family physician for review. Following discussion, it was VOTED to approve the concept of the program and refer it to the Public Affairs Committee for consideration and report back to the Council with recommendations including financial notes on any proposals.

Report of the Executive Director

Mr. Norbeck reported on the following items:

- (1) A response to a particularly offensive editorial which appeared in the New Haven Register and which was distributed to the Council with the agenda.
- (2) He discussed at length specifics of the Catastrophic Bill passed by the Congress in 1988. Financing mechanisms have been severely criticized by the elderly, and the House Ways and Means Committee approved of a compromise in July 1989. The compromise, however, shifts part of the burden from the more affluent seniors to those of modest means. This matter will be addressed by the Senate Finance Committee this month and resolved by Congress by the end of 1989.
- (3) Mr. Norbeck reported that, effective January 1, 1990, Rhode Island physicians must take Medicare assignment for all seniors, regardless of income. The only difference from the 1985 Massachusetts legislation is that the assignment issue will not be tied to licensure. Such action will most assuredly mean another thrust on the part of Connecticut's elderly for mandatory assignment.
- (4) He also discussed a meeting held in Albany, New York, which was attended by CSMS president, Roger Beck, M.D. and himself. The meeting included their counterparts from the states of New York, New Jersey, Pennsylvania, and Massachusetts. Dr. Beck and Mr. Norbeck explored the possibility of forming a Northeast Coalition of AMA delegations, comprised of the six New England states along with the other three represented at the meeting. The initial response appeared to be favorable.

Following Mr. Norbeck's report, the following actions were taken:

- (1) It was VOTED that CSMS explore the possibility of expanding the New England Coalition to the Northeast Coalition.
- (2) It was VOTED that an inquiry be directed to the Department of Aging as to progress being made in the courtesy card program; i.e., how the program is being advertised, how many seniors have been signed up since the program has been taken over by the state and is there a backlog of applications.
- (3) A motion and amendment that CSMS take immediate action to publicize, through newspaper ads, its regret at Congress shifting the cost of the Catastrophic Bill among the needy elderly was tabled until the

Council meeting following the House of Delegates meeting.

Nominations to CPRO Board

A communication was received from the Chairman of the Nominating Committee of CPRO requesting a nomination to replace William Whalen, M.D., who is ineligible to serve another term. Two names were requested and it was VOTED to submit the names of Drs. Juan Sosa and Kenneth Dardick.

Nominations for Positions on AMA Councils

It was VOTED unanimously to submit the following names to the AMA for possible appointment to the following Councils:

Council on Legislation: Jerome K. Freedman, M.D.

AMPAC Board: Stewart J. Petrie, M.D.

Council on Medical Service: Edward A. Kamens, M.D.

Report of the Committee on Legislation

Dr. Howard Wetstone, Chairman, reviewed the minutes of the Committee meeting held on August 3, which were distributed to members of the Council. Following discussion the following actions were taken:

- (1) VOTED that CSMS support legislative changes to the reporting requirements for physicians whose patients are high risk drivers.
- (2) VOTED not to address the inclusion of PA's into the Nurse Prescriptive Rights law until PA's are licensed and that CSMS should participate in the Department of Health Services committee on licensing of PA's and writing of regulations on the Prescriptive Rights law.
- (3) VOTED that CSMS approach the insurance industry about forming a coalition against any regressive changes in the tort laws.
- (4) VOTED that CSMS support regulation of PPO's and the regulations of activities of private utilization review firms.
- (5) VOTED to refer to the Committee on Allied Health a motion to enter into discussions with the Physicians' Assistants with a view of collecting information for the Council regarding PA's concerns about licensure, etc.
- (6) VOTED that the Committee on Legislation, in its coalition with the insurance industry, make every effort to limit payment for non-economic damages.

Committee on Geriatrics

Following is the action taken on two requests received from the subject committee:

- (1) VOTED that CSMS endorse the Geriatric Symposium to be held on October 9, 1989 at the Treadway Hartford Hotel in Hartford. No fiscal request was required for this program.
- (2) VOTED to have the Committee on Geriatrics pursue the proposal for a joint CSMS-AARP project involving a volunteer program for the nursing homes in the

state. Mrs. Reed, the CSMS Auxiliary President, offered the services of the Auxiliary in this project.

Report on ACCME Recognition of CSMS

Marvin Garrell, M.D., Chairman of the CME Committee, joined the Council to discuss the recent site visit of the national Accreditation Council for Continuing Medical Education (ACCME) for recognition of CSMS as Connecticut's CME accreditation agency. He gave a brief resume of the activities of the committee, its organization, and outlined what it does to enhance continuing education for physicians of the state. He reported that the members of the CSMS committee generously volunteer their time to make site visits to review the various hospitals for CME accreditation. A packet of information was distributed for the Councilors future reference which included data on all CSMS accredited organizations and those in the process of being reviewed. He paid tribute to Mr. Robert Brunell of the CSMS staff stating that the work of this committee could not be accomplished without his expert assistance. It was VOTED to receive Dr. Garrell's report as information and with commendation.

Advisory Committee to New Haven Welfare Department

A request was received from William T. Lee, Director of the Department of Welfare for New Haven, for a nomination to a Professional Advisory Committee to advise the Welfare Department concerning professional standards, and the program policies for health care related matters covered by the medical services contract for general assistance recipients of the Hill Health Center of the City of New Haven. It was VOTED to submit, in the following order, the names of (1) Myron Genel, M.D. and (2) Richard H. Greenspan, M.D., both of New Haven, to Mr. Lee.

Report from Delegate to Connecticut Nutrition Council

Vincent Catrini, M.D., the CSMS delegate to the Connecticut Nutrition Council, reported that the group is involved in setting diet modification programs for schools. Videos have been developed and meetings have been held with various school boards in the state. The program will bring to the schools the newer recommendations that come from the National Academy of Science and the Surgeon General. He requested that CSMS send a letter to Gerald N. Tirozzi, Commissioner of Education, that a nutrition program is being developed for the schools of Connecticut under the auspices of CSMS and that we would like his endorsement for dissemination of the information to the superintendents in Connecticut's schools. It was VOTED to approve Dr. Catrini's request.

Resignation-Delegate to AMA

It was VOTED to accept with regret the resignation of Vincent Catrini, M.D. as Delegate to the AMA. Dr. Catrini submitted his resignation due to the pressures of his other activities and felt that he could not devote the

time that this office required. The Council expressed their appreciation for all of his efforts on behalf of the Society and gave him a standing ovation. It was further VOTED that the small counties be asked to bring in a nomination for this post at the next Council meeting.

Connecticut Medical Insurance Company (CMIC)

Mehdi Eslami, M.D., Chairman of Connecticut Medical Management Incorporated (CMMI) reported that exactly five years ago, CSMS voted to establish CMIC which is now a viable organization. He briefly outlined what CMIC has accomplished in Connecticut.

1. On October 1, 1984, the first policies were sold.
2. Effective January 1, 1990, there will be a rate decrease for all classes and limits up to 6.2%.
3. CMIC continues the risk management premium credit program and the self study course.
4. CMIC is developing innovative insurance programs for physician groups and hospital medical staff groups to introduce premium savings and risk management incentives.
5. CMIC has enhanced the retirement benefits. Free "Tail" (Extended reporting policy period endorsement) available October 1, 1989 to members retiring at age 60 with five years of continuous coverage by CMIC. Credit program for "tail" purchase continues for members retiring after age 55. Pre-retirement waiver of "prior acts" adjustment for qualified members approved.
6. CMIC offers defendant support group programs open to members, involved in the claims resolution process, and their spouses. Individual defendant counseling offered by peers. A defendant support manual is available as a resource to members.
7. CMIC is publishing a Member Handbook as a guide to CMIC physicians for important coverage and claims questions.

Dr. Eslami stated that most of the above programs are unique to CMIC and that they are very proud of these programs. Dr. Eslami then reviewed the statistics dealing with premiums, financial position of CMIC, membership, claims, etc. He further stated that the members of CSMS deserved commendation for having foresight in developing CMIC, CPRO and M.D. Health Plan.

Building Committee

It was VOTED that a building committee be appointed, including representatives of CMIC, CPRO and M.D. Health Plan, to investigate the possibility of housing all organizations under one roof.

N.B.: *The foregoing is a summary of the proceedings and actions of the Council on September 7, 1989. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for purusal by any interest member of the Society.*

CSMS PHYSICIAN PLACEMENT SERVICE

The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

Listing of physicians in the Placement Service does not in any way represent certification by the Society. Investigation of credentials and experience is the responsibility of those seeking applicants for positions.

OPPORTUNITIES FOR PRACTICE

AMBULATORY CARE

Full time position available for an ambulatory care physician to work in an established walk-in center in the greater Bridgeport area. Broad general medical experience requiring minor surgery, orthopedics and excellent diagnostic skills; family practice, emergency medicine, internal medicine preferred. Connecticut license required at the time of application. Salary and benefit package commensurate with experience. Please send CV to Immediate Health Care, 15 Armstrong Rd., Shelton, CT 06484, Attn: Darlene Breving.

Full time or part time position available for physician (preferable background in Family Practice or Internal Medicine) in established Walk-In Center in Branford, CT. Pleasant working conditions; competitive salary; shoreline location. Please send CV to: Harry Ardolino, M.D., Coastline Medical Center, 9 Business Park Dr., Branford, CT 06405 or phone (203) 481-0818.

FAMILY PRACTICE

Opportunity to join existing, busy board certified family practitioner in a growing shoreline community. Family community, growing practice, desirable location with full range of family medicine except OB. If interested, please send reply to CSMS, c/o FP/BA.

INSTITUTIONAL AND INDUSTRIAL MEDICINE

Urgent visit physicians. CHCP, a pre-paid Staff Model HMO in its eighteenth year of service with over 68,000 members is seeking Urgent Visit/E.R. physicians for positions currently available and for positions which will start within the next year. Affiliations with prestigious institutions such as Yale New Haven Hospital enable our staff to provide high quality medical care while offering opportunities to maintain clinical skills in the setting of an established HMO. Highly competitive compensation package. Send CV along with salary requirements in confidence to: Charles Hollander, M.D., Medical Director, Community Health Care Plan, Inc., 150 Sargent Dr., New Haven, CT 06511. (203) 781-4100, Fax (203) 562-2802. We are an equal opportunity employer.

Dutcher Treatment Center, a 96-bed facility, a leading public facility dedicated to the treatment of chemical dependency and a component of the Connecticut Alcohol and Drug Abuse Commission (CADAC), is seeking a full-time Internist/Family Practitioner/Surgeon to function as the Director of Admissions of the acute treatment and evaluation

unit. We offer a competitive salary based on a 35-hour week and an excellent benefit package. Dutcher Treatment Center is located on a scenic campus in Middletown, close to the shoreline and convenient to New Haven and Hartford. If you are interested in challenging work in the management of chemical dependency, contact: Ms. Gladys Traverso, Dutcher Treatment Center, P.O. Box 543, Middletown, CT 06457 or call (203) 638-5805. E.O.E. - M/F.

INTERNAL MEDICINE

Internist needed to join busy young solo practitioner in Fairfield County. Salary, benefits and opportunity for partnership. Please respond to: CSMS, c/o IM/EM.

Internist BC/BE wanted to join private pharmaceutical research corporation. Excellent part time opportunity for combining primary care experience with medical research responsibilities. Send CV to: Medical Director, National Medical Research Corp., 25 Main St., Hartford, CT 06106.

Internist BC/BE with or without subspecialty interest to join five person internal medicine group. Mystic-New London, CT; excellent benefits; early partnership. Write CSMS, c/o IM/CD.

Two busy Pulmonologists/Internists/Critical Care specialists in Hartford suburb are seeking an associate/partner. Modern 200-bed community hospital; opportunity for university affiliation; competitive financial and benefit package; central Connecticut location. Estimated 20% internal medicine during first year with increasing pulmonary/ICU as practice builds. Candidate should be BC in Internal Medicine and BC/BE in Pulmonology/Critical Care. Special qualifications negotiable. Please reply with CV to PULMONARY ASSOCIATES OF BRISTOL, Suite D25, 25 Newell Rd., Bristol, CT 06010.

Internal Medicine/Family Practice—To join very successful Internal Medicine group in coastal Southeastern Connecticut. Call or mail CV to: William A. Colom, M.D., 447 Montauk Ave., New London, CT 06320. (203) 447-1426.

Internist or Internist/Specialist to join well established three physician Internal Medical Group in New Haven to practice Internal Medicine. Close association with both hospitals and Medical Center. Write: David B. Melchinger, M.D., 100 York St., New Haven, CT 06511.

A competent, caring, BC internist, with or without subspecialty, for expanding, high-quality, two-person Internal Medicine practice in New Haven county. Immediate opening. Competitive salary with incentive; possible partnership. Send CV and salary requirements to CSMS, IM/VV.

INTERNAL MEDICINE/FAMILY PRACTICE

Immediate Medical Care Center is seeking physicians with the expertise and desire to practice high quality academic, industrial medicine as well as aggressive primary clinical medicine at our new industrial care center. Located in the South End of Hartford, this 6,000 foot center will serve a major industrial population and function as a significant community medical resource. The industrial care center is affiliated with the largest teaching hospital in the state and will be the only center of its kind in Central Connecticut. Interested physicians are encouraged to contact us by early October so they can participate in the design of the center which is scheduled to begin operation in January 1990. Immediate Medical Care Center is also seeking a physician interested in practicing aggressive primary care medicine in a community based practice. Physicians interested in either position should contact: Gregg Grinspan, M.D., Medical Director, Immediate Medical Care Center, 5 Hillcrest Ave., Wethersfield, CT 06109. Phone: (203) 721-7393.

MISCELLANEOUS

School Physician vacancy in New Britain, CT School District. Physician needed to plan, direct, and supervise health services in our school district. Must be licensed to practice medicine in Connecticut. Salary open. Apply to: William Colton, Personnel Manager, New Britain School District, One Liberty Square, New Britain, CT 06051 or call (203) 827-2249. E.O.E.

OPHTHALMOLOGY

For Sale. Eye Surgeon Practice; well-known. University town. Connecticut license and own malpractice needed. Write, P.O. Box 1085, Orange, CT 06477.

ORTHOPEDIC SURGERY

Orthopedic surgeon; board eligible or certified to join solo practice. Interest in spine and trauma necessary. Two 500-bed Yale affiliate hospitals. Write CSMS, c/o ORTH/FT.

PEDIATRICS

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Type III Membranoproliferative Glomerulonephritis in Primary Sjögren's Syndrome

IRA SCHLESINGER, M.D., TERRY S. CARLSON, M.D., AND DAVID NELSON, M.D.

ABSTRACT—Glomerulonephritis is a rare complication of primary Sjögren's syndrome. When glomerulonephritis does occur, it is usually due to membranous, focal proliferative, or membranoproliferative lesions. There have been fewer than 20 reported cases of glomerulonephritis in primary Sjögren's syndrome, only three of which have been membranoproliferative. We report a case of primary Sjögren's syndrome complicated by Type III membranoproliferative glomerulonephritis, a specific type of mesangiocapillary glomerulonephritis never before reported in this setting, and describe a clinical course terminating in rapidly progressive renal failure.

Introduction

SJÖGREN'S syndrome is an immunologically mediated disease resulting in xerophthalmia and xerostomia, ie, the sicca complex. Primary Sjögren's syndrome is defined as the sicca complex in the absence of some other autoimmune disorder. Secondary Sjögren's syndrome is defined as the sicca complex coexisting with another autoimmune disease, most frequently rheumatoid arthritis or systemic lupus erythematosus.¹ Extraglandular manifestations of primary Sjögren's syndrome are common and include cerebral vasculitis, myositis, interstitial lung disease and interstitial nephritis.^{1,2,3} Although interstitial disease is the most common renal lesion,⁴ there have been sporadic case reports of primary Sjögren's complicated by glomerulonephritis (GN).⁵⁻¹¹ In all cases in which a distinctive lesion was identified, the histopathology was either membranous, focal proliferative, or membranoproliferative.⁵⁻⁸ Membranoproliferative glomerulonephritis (MPGN) has been subdivided

into three distinct variants, their common features being proliferation of mesangial cells and extension of both mesangial cells and matrix into the peripheral capillary wall. Type I is characterized by subendothelial electron dense deposits, Type II by intramembranous deposits and Type III by both subendothelial and subepithelial deposits.^{12,13} Although Type I MPGN has been previously described in primary Sjögren's syndrome, our patient fulfilled the criteria for Type III MPGN. Such a diagnosis, to our knowledge, has never before been made in this setting.

Case Report

The patient is a 73-year-old white woman with a past medical history of primary Sjögren's syndrome and hypothyroidism, both diagnosed in 1978, and a two-year history of proteinuria. Three days prior to admission she was noted to have a blood pressure of 160/100. A 24-hour urine specimen contained 7g of protein. On the day of admission, she was seen in the emergency room with progressive shortness of breath, swelling of her extremities, dyspnea on exertion, and orthopnea. She denied having chest pain, palpitations, or diaphoresis. She had never received gold or penicillamine therapy, nor had she any known exposure to hydrocarbons or any recent infections. Her only medication was levothyroxine.

On physical examination her blood pressure was 200/100. The conjunctivae were bilaterally injected, mucous membranes were dry, and bilateral parotid gland swelling was present. Bibasilar rales were present; examination of the heart revealed tachycardia without murmurs, rubs, or gallops. There was 2+ pitting edema of the lower extremities; her joints were not swollen and she did not have a rash.

An electrocardiogram revealed a supraventricular tachycardia with a rate of 200. A chest roentgenogram showed mild pulmonary vascular congestion without infiltrates or effusions. The urine specific gravity was 1.008, pH 6, 4+ protein, trace heme, 25 RBC/HPF and 0-1 WBC/HPF. No white or red blood cell casts were present. The serum sodium was 136 mmol/dl, potassium 4.3 mmol/dl, chloride 111 mmol/dl, bicarbonate 20.8

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mmol/dl, blood urea nitrogen 31 mg/dl, creatinine 1.7 mg/dl, calcium 8.2 mg/dl (8.6-10.8 mg/dl), albumin 2 g/dl. CPK isoenzymes were 100% MM fraction. Erythrocyte sedimentation rate was 113 mm/hr. Hemoglobin was 8.6 g/dl and hematocrit was 25.3%. Serum iron was 45 μ g/dl (55-185 μ g/dl range) and total iron binding capacity was 123 μ g/dl (250-425 μ g/dl). Reticulocyte count and corrected reticulocyte index were 1.1% and 0.7% respectively. A direct Coomb's test was negative. Thyroid function tests showed a TSH of 54.4 μ IU/ml (0.29-5.1 μ IU/ml) with a normal free and total T_4 . Anti-thyroglobulin antibodies were positive at a dilution of >1:20 (nl=<1:10). Antimicrosomal and antimitochondrial antibodies were not present. ANA was positive in a dilution of 1:1280 in a homogeneous pattern. LE cell prep was negative. Antibodies to dsDNA, performed by radiometric binding assay, were normal at less than 1 unit/ml (0-1 unit/ml). Antibodies to ssDNA, also performed by radiometric binding assay were normal at less than 1% binding (0-6% binding). Antibodies to ribonuclear protein (RNP), Smith antigen (Sm), and histones were absent. Both anti-SSA (Ro) and anti-SSB (La) antibodies were present. RPR and hepatitis B surface antigen were negative. ASO titer was normal. Rheumatoid factor was positive at a dilution of 1:320. A Schirmer's tear test was abnormal with less than 4mm wetting in each eye. Cryoglobulins were negative. C3 measured less than 50 mg/dl (83-177 mg/dl); C4 was less than 8 mg/dl (15-45 mg/dl). CH50 was 20% (51-150%). Quantitative serum immunoglobulin levels were within normal limits. Urine immunoelectrophoresis showed an albumin band of 56% (38% upper normal), a gammaglobulin zone of 16% (3% upper normal), and a polyclonal increase in both kappa and lambda free light chains. C1q binding was 5% (<13% normal). Raji cell immune-complex assay was markedly elevated at 194 μ g AHG eq/ml (0.0-50.0 μ g AHG eq/ml). Antisalivary duct antibody assayed by indirect immunofluorescence using fresh frozen guinea pig salivary gland was positive at a dilution of 1:20.

The patient's supraventricular tachycardia was treated with electrical cardioversion after which time her shortness of breath resolved. A follow-up electrocardiogram revealed a sinus tachycardia with a rate of 120 without ischemic changes. The patient was given digoxin and verapamil to control her heart rate. Her only additional medications were prazosin, furosemide, and maintenance levothyroxine.

One week after admission the patient's BUN and serum creatinine rose to 71 mg/dl and 2.3 mg/dl, respectively. At that time the patient experienced a generalized tonic-clonic seizure. An electroencephalogram showed diffuse bilateral slowing and a noncontrast computed tomographic scan of the head was unremarkable. A lumbar puncture was normal. On hospital day 14, BUN and creatinine levels had risen to 87 mg/dl and 4.3 mg/dl, respectively. A renal ultrasound examination

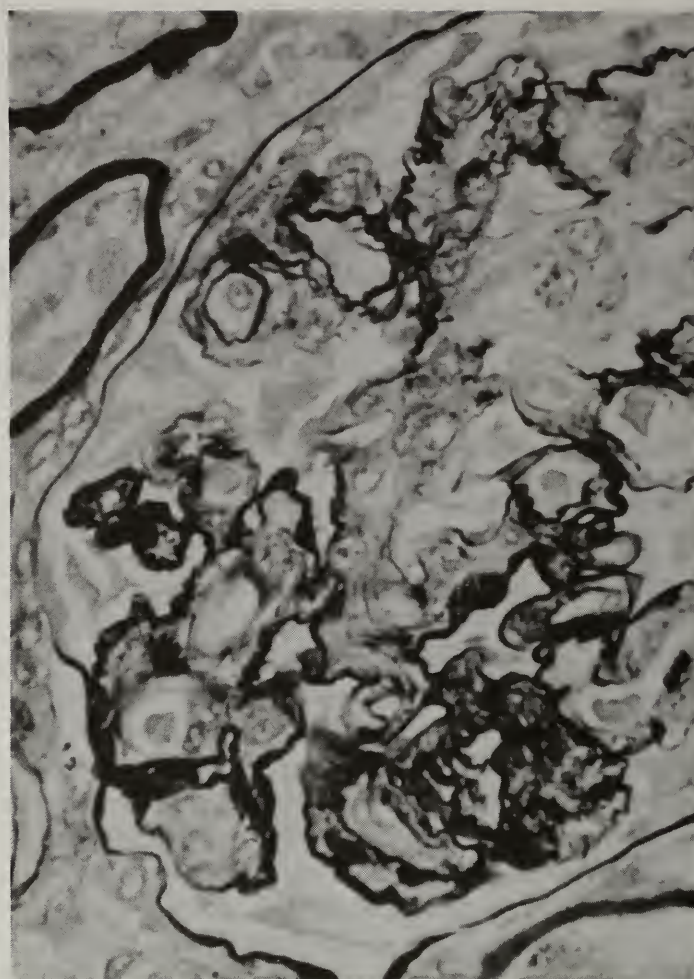


Figure 1

A glomerulus showing several capillary loops with a double contoured, reduplicated basement membrane, the "tram-track" sign of MPGN (original magnification x 1000, Jones silver stain).

revealed normal sized kidneys without evidence of renal vein thrombosis. An open renal biopsy was performed which revealed an immune-complex GN characterized by a thickened basement membrane, proliferation of mesangial cells, subepithelial and subendothelial electron dense deposits, and mesangial extension into the peripheral capillary wall. At this time therapy with pulse methylprednisolone and cyclophosphamide was instituted. The BUN and creatinine continued to rise and she became progressively oliguric and edematous. On day 21 the creatinine clearance was 4.6 ml/min and proteinuria had decreased to 2 g/day. The maximum BUN of 116 mg/dl and creatinine of 6.8 mg/dl were noted on the 28th day of hospitalization. Plasmapheresis with albumin replacement was begun without effect, and peritoneal dialysis was instituted. The following month of hospitalization was marked by a progressive decline in consciousness to the point of coma and finally cardiac arrest two months after admission. A repeat renal biopsy was performed within 15 minutes of the patient's death. Postmortem examination of minor salivary gland tissue was also performed.

Pathological Findings

The postmortem renal biopsy was prepared for light

microscopy, electron microscopy, and immunofluorescent studies. H & E staining revealed a "lobular" glomerular architecture with peripheral capillary wall thickening, mesangial hypercellularity, focal segmental and global sclerosis, and fibrous crescents. Patchy tubular atrophy with interstitial fibrosis was also noted. Jones silver staining (Fig. 1) showed a double contoured basement membrane, the "tram-track" sign consistent with MPGN. Basement membrane "spikes" were not seen. Electron microscopy (Fig. 2) revealed Type III MPGN, showing numerous dense deposits both within subendothelial and subepithelial regions. The basement membrane "spikes" between these subepithelial deposits were short, explaining why they were not seen with the silver stain. Mesangial cells were seen infiltrating the peripheral capillary loops causing splitting of these walls and reduplication of basement membrane matrix. Immunofluorescence microscopy revealed a diffuse, finely granular deposition of IgA with both kappa and lambda light chains localized primarily in the peripheral capillary walls. Antisera to IgG, IgM, C3, and fibrinogen were nonreactive. Postmortem examination of minor salivary gland tissue revealed normal cellularity and architecture. Pathologic examination of the cranial structures showed extensive bilateral occipital lobe encephalomalacia.

Discussion

The diagnosis of primary Sjögren's syndrome in our patient was made on the basis of several clinical and laboratory parameters. Anti-SSA (Ro) and anti-SSB (La) antibodies are known to occur in primary Sjögren's syndrome, secondary Sjögren's syndrome associated with systemic lupus erythematosus, and in certain subsets of systemic lupus erythematosus alone, namely subacute cutaneous lupus erythematosus, ANA negative lupus, and neonatal lupus.^{1,14} Antisalivary duct antibodies occur in primary Sjögren's syndrome, secondary Sjögren's syndrome associated with rheumatoid arthritis, as well as in rheumatoid arthritis alone.^{1,15} Our patient was anti-SSA (Ro), anti-SSB (La), and antisalivary duct antibody positive. She did not fulfill the diagnostic criteria for either systemic lupus erythematosus or rheumatoid arthritis. This serologic and clinical picture is consistent only with primary Sjögren's syndrome.

Although a rheumatoid factor was present, the patient had no clinical evidence of arthritis. Rheumatoid factor is a common finding in primary Sjögren's syndrome.^{4,15} Although an ANA was strongly positive, the only specific nuclear antigenic substances identified were SSA (Ro) and SSB (La); anti-dsDNA, ssDNA, RNP, Sm, and histone antibodies were repeatedly negative. This is highly suggestive of primary Sjögren's syndrome and is inconsistent with systemic lupus erythematosus. Additionally, the absence of anti-DNA antibodies is very unlikely in glomerular disease caused by systemic lupus erythematosus.⁴

Low serum complement levels, as present in this case, are not typically found in primary Sjögren's syndrome;

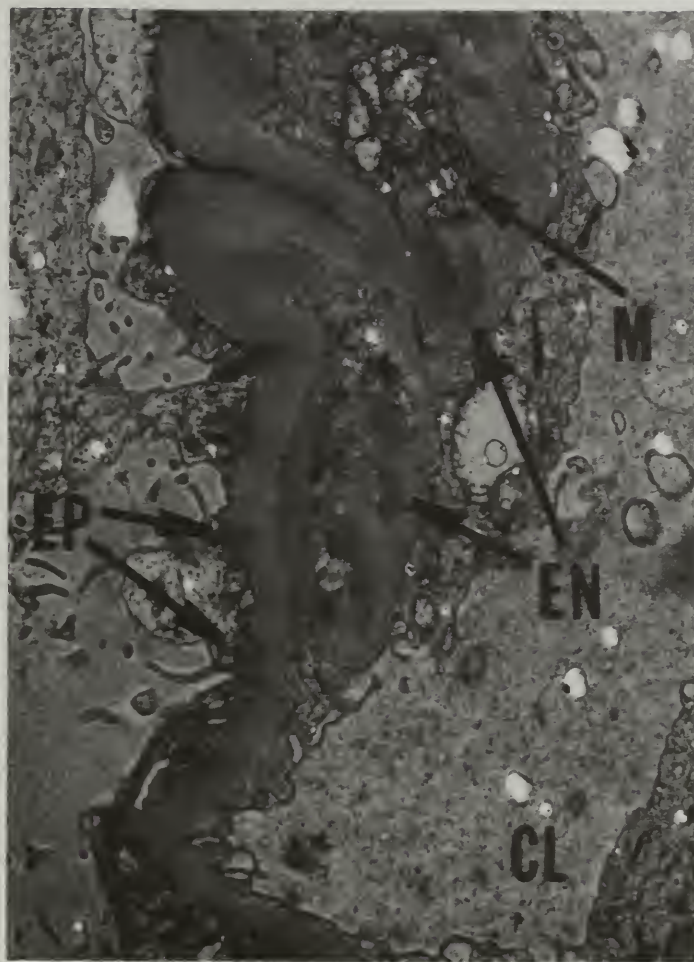


Figure 2

Electron micrograph demonstrating a capillary loop with mesangial cell interposition (M) and electron dense deposits located on both the subepithelial (EP) and subendothelial (EN) sides of the basement membrane. (CL) is a capillary lumen (original magnification x 3041).

however, reduced serum C3 levels are characteristic of MPGN. Furthermore, low serum complement levels have been previously documented in primary Sjögren's syndrome complicated by both MPGN and membranous GN.⁶

This case illustrates that primary Sjögren's syndrome is actually a multisystem autoimmune disorder. Serologic markers for autoimmune thyroiditis were present. The markedly elevated Raji cell assay is indicative of circulating immune complexes. Autoimmune GN was clearly documented. In addition, although we did not obtain pathologic evidence of cerebral vasculitis, the postmortem finding of bilateral occipital lobe infarcts is suspicious for vasculitis. The presence of anti-SSA (Ro) antibodies defines a subset of patients with primary Sjögren's syndrome who have a predilection for the development of central nervous system (CNS) vasculitis.² We believe it is unlikely that this broad spectrum of autoimmune involvement occurred by chance in a patient with primary Sjögren's syndrome. Antithyroid antibodies,⁴ a positive Raji cell immune complex assay,¹⁶ GN,⁵⁻¹¹ and CNS vasculitis² are all well documented findings in primary Sjögren's syndrome. Furthermore, although primary autoimmune thyroiditis has been reported in association with various types of

GN,¹⁷⁻¹⁸ MPGN, to the best of our knowledge, has not been reported. It is therefore most likely that the autoimmune thyroiditis, circulating immune complexes, MPGN, and CNS vasculitis were all complications of primary Sjögren's syndrome.

It is unfortunate that a minor salivary gland biopsy was not performed prior to immunosuppressive treatment. The typical lesion of focal lymphocytic infiltration seen in Sjögren's syndrome has been shown to regress with cyclophosphamide therapy alone.¹⁹ We strongly suspect that any glandular infiltrate would have been reversed by treatment with the combination of cyclophosphamide, methylprednisolone, and plasmapheresis.

We performed both premortem and postmortem renal biopsies in order to observe the pathologic progression during this clinically virulent course. Although MPGN was present in both biopsy specimens, the postmortem specimen showed a greater degree of mesangial extension into the peripheral capillary loops and had the appearance of an end-stage kidney. Such an outcome is atypical in that most reported cases of Type III MPGN have not resulted in end-stage renal failure^{12,13} and there have been reports of improvement with immunosuppressive therapy.¹³ However, the presence of the nephrotic syndrome at presentation in Type III MPGN has been shown to be an important indicator of ensuing end-stage renal disease despite prednisone therapy.¹³

Of the less than 20 reported cases of GN in primary Sjögren's syndrome,⁵⁻¹¹ only three have been classified as MPGN.^{5,6} In 1978 Moutsopoulos and coworkers⁶ described two cases of MPGN in primary Sjögren's syndrome. The first was characterized by subendothelial electron dense deposits, increased mesangial cellularity, and mesangial interposition. These findings were suggestive of Type I MPGN. Subtyping of the second case of MPGN was not possible because of technically unsatisfactory electron microscopy. In 1986 Siamopoulos and coworkers⁵ reported an additional case of MPGN in primary Sjögren's syndrome. Electron microscopic findings were not included and subtyping was not described.

We here report an additional case of the rare association between primary Sjögren's syndrome and GN. Our patient suffered from MPGN, a lesion which has been reported on only three previous occasions. The association between Type III MPGN and primary Sjögren's syndrome has to our knowledge never before been described.

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Airway Intubation in Injured Patients at the Scene of an Accident

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ROBERT J. SCHWARTZ, M.D., M.P.H., AND SHERRY A. STOHLER, R.N.

ABSTRACT—Trauma patients requiring intubation at the scene of the accident were entered into a study from June 1985 to June 1987 to determine: 1) the success rate of intubation by flight crews and 2) factors important in managing the difficult airway at the scene. One hundred thirty-six patients were reviewed. The success rate of trauma patients intubated in the field was 92.6%. The success rate of each procedure was, orotracheal 87%, and nasotracheal 77.6%. Six out of the 10 patients unsuccessfully intubated had vomiting or blood in the oropharynx which was cited as the reason for failure of intubation. All 24 patients requiring medications (paralytics and sedatives) for intubation were successfully intubated. Trismus and combativeness were the indications for medication usage. An aeromedical crew (MD, RN, RT) can successfully intubate trauma patients at the scene of the accident. Severe facial injuries with vomiting and blood in the oropharynx are factors in intubation failure. The use of muscle relaxants and sedatives facilitates difficult intubations.

Introduction

THE increased use of advanced life support skills in the prehospital care of trauma patients has contributed to a reduction in early mortality.^{1,2,3,4} Rapid transport is critical in patients injured close to a trauma center; however, this may be difficult in patients sustaining injury in a rural setting. Vital components of prehospital care include control of the airway, adequate ventilation, minimizing hemorrhage, and volume resuscitation. The latter may be performed while enroute to a trauma center.

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Airway control is the most challenging prehospital task. Management of hemorrhage at the scene is limited to manual compression or pneumatic antishock garment (PASG) inflation. In volume resuscitation, physiologic computer modeling demonstrates that intravenous fluid is of benefit only if the time from injury to emergency department arrival exceeds 30 minutes, the IV infusion rate is approximately equal to the bleeding rate, and the rate of bleeding is initially 25-100 ml/min.⁵

Hypoxemia and hypotension may worsen the outcome in patients with severe closed head injuries, doubling the mortality from 24% to 53%.⁶ Therefore, utilization of definitive airway control with hyperventilation and hyperoxygenation as early as possible may affect survival and outcome in head injured patients. The preferred method of airway control in critically injured patients is endotracheal intubation.⁷ Problems specific to endotracheal intubation in the trauma patient include inability to position the patient optimally with the need to maintain in-line traction, head injury associated with combativeness and trismus, facial or laryngeal fractures obstructing passage of the tube, blood or vomitus in the oropharynx precluding adequate visualization of the vocal cords, and suboptimal illumination and suction equipment at the scene of the accident.⁸ The trauma patient is characteristically a young male and usually muscular with a full set of teeth. Combining all of these factors presents major challenges to intubation. However, the need for definitive control of the airway is essential for optimal care, especially in those patients with head injuries.

The purpose of this study was to determine the success rate of intubation of trauma patients at the scene of the accident by an aeromedical crew, to identify groups of patients at the scene who are difficult to intubate, and to assess the use of medications in performing these intubations.

Methodology

All trauma patients transported by an aeromedical crew from the scene of the injury and requiring intubation from June 1985 through June 1987 were entered into the

study. Data were collected after each flight and entered into a computer registry. The indications for intubation were traumatic cardiac arrest, head injury, respiratory distress, airway obstruction, or some combination of these indications (Table 1).

Table 1
Indications For Intubation

	(n=# of patients)
Traumatic Arrest	36 (26%)
Head Injury	34 (25%)
Head Injury/ Agonal Respirations	30 (22%)
Head Injury/Tachypnea	21 (15%)
Respiratory Distress	7 (5%)
Head Injury/Obstructed Airway	7 (5%)
Obstructed Airway	1 (1%)

The aeromedical crew consists of a pilot, emergency medicine physician, flight nurse, and respiratory therapist. All physicians are certified in advanced cardiac life support and advanced trauma life support. The flight nurse training program is an intensive four month course with didactic lectures and clinical rotations in each of the major subspecialties. Certification as a paramedic is included in the program. Experience with intubation is obtained by mannikin instruction and operating room experience.⁹ The respiratory therapists are certified at the emergency medical technician - intermediate level. Their main role is maintaining the airway and providing adequate ventilation after intubation.

The flight nurse is the primary performer of the intubations at the scene. If this is unsuccessful after two attempts, each less than thirty seconds in duration, the physician attempts the procedure. The method of intubation and the use of medications for the intubation are discussed by the physician and flight nurse during the performance of the procedure. If all attempts are unsuccessful the patient is ventilated with the bag-valve-mask technique. The indication for performing a cricothyroidotomy at the scene is the inability to auscultate breath sounds with bag-valve-mask ventilation after failed endotracheal intubation.

The nasotracheal route of intubation is preferred if the patient has spontaneous respirations. The orotracheal route is used if the patient is not breathing or nasotracheal intubation is unsuccessful. If the patient has craniofacial disruption or fracture of the bony architecture of the maxilla, nasotracheal intubation is not attempted. Various combinations of paralytic agents and sedatives are utilized to accomplish intubation if the patient is combative with resistance to intubation or has trismus. An assessment of the ability to maintain an airway is performed prior to the use of medications. Medications used in this study include succinylcholine, vecuronium bromide, diazepam, and morphine sulfate.

Detailed descriptions of each case were recorded at the conclusion of the flight and entered into a computerized trauma registry. Information collected was: mechanism of injury, age, type of injuries sustained, scene time, scene Glasgow coma scale and trauma score, type of intubation, medications used and dosages, and physical examination characteristics, such as blood about the face, nares, or in the oropharynx, vomiting, unstable facial bones, neck edema, unstable neck (exclusive of suspected cervical spine injury), and subcutaneous air. Obesity was recorded only in the unsuccessful category of patients. The reasons for the unsuccessful intubations were recorded.

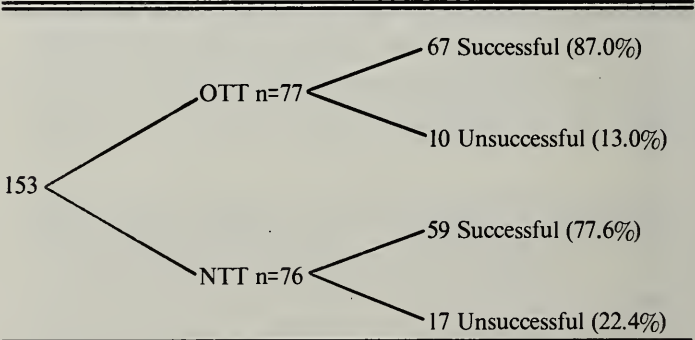
To assure high quality decision making in the use of medications and to maintain intubation skills, an aggressive quality assurance program exists. Review of all helicopter transported patients is conducted biweekly with medical control physicians and the medical director of the flight unit. The flight nurse must present the case and discuss all indications for advanced life support procedures. Difficulties in endotracheal intubation are followed by formal instruction and skill maintenance in the emergency department or operating room.

Chi square (X^2) analysis and analysis of variance were used to identify evidence of statistical significance or associations of subgroups.

Results

One hundred thirty-six trauma patients from a total of 310 trauma patients required intubation at the scene of the accident. There were 106 (77.9%) males and 30 (22.1%) females ranging from ages one through 86. Scene Glasgow coma scale (GCS) ranged from three to 15 (mean GCS=5) and scene trauma scores (TS) ranged from one to 14 (mean TS=7). One hundred twenty-six patients were successfully intubated (92.6%). Approximately half of the intubation attempts were orotracheal, 50.3% (n=77), and half were nasotracheal 49.7% (n=76), with success rates of 87.0% and 77.6% by procedure respectively (Table 2). When one method failed the other was attempted, if indicated, yielding a higher overall success rate.

Table 2
Scene Trauma Intubations By Procedure



A comparison of mechanism of injury and success of intubation is listed in Table 3. Motorcyclists, bicyclists, and patients falling more than eight feet appear to be more difficult to intubate, but their numbers were not statistically significant.

Table 3 Mechanism of Injury and Success Rate of Intubation		
Mechanism of Injury	Number of Patients (TOTAL)	Successfully Intubated
MVA	84 (61.8%)	80 (95.2%)
MCA	19 (14.0%)	16 (84.2%)
Pedestrian	14 (10.3%)	13 (92.9%)
Bicycle	6 (4.4%)	5 (83.3%)
Fall >8 ft.	5 (3.7%)	4 (80.0%)
GSW	4 (2.9%)	4 (100.0%)
Fall <8 ft.	2 (1.5%)	2 (100.0%)
Blunt/crush	2 (1.5%)	2 (100.0%)
	136 (100.0%)	126 (92.6%)

The ages of patients follow national age distributions for trauma patients. The majority of patients were between the ages of 16-44. The patient's ages were grouped in three categories: those less than eight years of age, age eight to 55, and greater than 55. An analysis of variance demonstrated an association between the age groups and success rate of intubation. The older age group was associated with a lower success rate of intubation (p=.0063).

Of the six physical examination characteristics, blood on the face and nares was most frequently present, n=81 (59.5%), followed by 44 patients who had blood in the oropharynx and vomiting (32.3%). The number of physical examination characteristics identified in each patient were totaled and ranged from zero to three. Table 4 compares the sum totals of examination characteristics with intubation success rates. Sixty percent of unsuccessfully intubated patients had two or three characteristics. Patients that suffered from multiple findings had lower success rates of intubation, but these numbers were not statistically significant.

Table 4 Total Number of Physical Exam Characteristics By Intubation Success Rate			
Total Number PE Char.	Intubation		Total
	Unsuccessful	Successful	
0	2 (20%)	39 (31.0%)	41
1	2 (20%)	44 (34.9%)	46
2	4 (40%)	27 (21.4%)	31
3	2 (20%)	16 (12.7%)	18
	10	126	136

When grouped according to TS,¹⁰ the more severe physiologically injured patients had higher numbers of facial physical examination characteristics (Table 5). The group with severe physiologic derangement (TS < 6) had significantly more facial anatomical injuries compared to the moderately and mildly injured groups.

Details of the ten unsuccessfully intubated patients are listed in Table 6. Six out of the ten patients had vomiting or blood in the oropharynx as the primary reason for a failed intubation.

Twenty-four patients (17.5%) required medications

for intubation (Table 7). All of these patients were successfully intubated. Only 4.3% (n=3) of patients with GCS < 5 required medications for intubation while 31.3% (n=21) of patients with GCS > 5 required medication for intubation. Indications for the use of medications are listed in Table 8.

A learning curve for operators may have been demonstrated in that 40% of the failed intubations occurred during the first six months of the flight program.

Discussion

Airway control is an important aspect of prehospital care which may substantially affect patient morbidity, mortality, and functional outcome. Definitive airway control is not without risks in injured patients. Inserting a nasotracheal tube in a patient with an unstable midface

Table 5 Trauma Score and Average Number Physical Exam Characteristics			
Trauma Score (TS)	Mean PE Char/ PT	Standard Error	95% Confidence Limit
TS > 12 (n=9)	.66	.235	.19, 1.13
TS> 6 and < 12 (n=82)	1.06	.105	.85, 1.27
TS < 6 (n=45)	1.53	.164	1.20, 1.86

has the potential of tube misplacement because of disruption of the nasopharynx. Extension of the neck is absolutely contraindicated in trauma patients because of the possibility of cervical spine injury. In-line traction must be maintained during this procedure. Paralytics may facilitate orotracheal intubation by relaxing musculature so that in-line traction may be held. Although there are risks associated with intubating trauma patients at the scene of an accident, there are substantial benefits of early definitive airway control. As many as 65% of non-intubated head injured patients arrive in the emergency department hypoxemic despite no obvious respiratory distress.¹¹ Extension of brain injury is thought to occur with prolonged hypoxemia and the presence of persistently high intracranial pressure.^{12,13} Aspiration of blood or vomitus and depressed respiratory function are factors which cause hypoxemia in head injured patients. These factors may be controlled by intubation of the airway. Since head injury is the primary contributor of early mortality in multiple injured patients,¹⁴ earlier intubation of the airway in trauma patients may result in improved outcome.

Debate exists over the best method of airway control for the trauma patient at the scene of the accident. Although widely in use and requiring minimal training for insertion, the esophageal obturator airway (EOA) and esophageal gastric tube airway (EGTA) fail to provide optimal airway control and significant complications have been reported.^{15,16,17,18,19} A prospective study comparing arterial blood gases from patients with the

EGTA in the prehospital setting to samples obtained after endotracheal intubation in the emergency department showed significant impairment of both oxygenation and ventilation with the EGTA.²⁰ Endotracheal intubation is the optimal method of definitive airway control provided adequate training for the procedure has been established.²¹

A high success rate of endotracheal intubation was achieved by an aeromedical flight crew without early complications. Orotracheal and nasotracheal techniques were used with equal frequency but with specific indications. Digital²² and transillumination techniques²³ of intubation were not utilized but may be incorporated into the procedures performed by the crew in the future. No patients in this series required cricothyroidotomy since an effective seal was obtained with bag valve mask ventilation in the unsuccessfully intubated patients. This method of airway control in the field was preferred to a surgical approach.

Table 6
Unsuccessfully Intubated Patients

	Indication	Airway Control	Reason for Failure
M14 (MVA)	RR<10, shallow head injury	(-) OTT Bag-valve mask	Vomiting
M48 (MVA)	RR<10, shallow head injury	(-) OTT (-) NTT Bag-valve mask	Unstable Mandible/ maxilla
F30 (MVA)	RR<10, blunt chest trauma head injury	(-) OTT (-) NTT Bag-valve mask	Vomiting
F36 (Ped.)	RR<10, shallow head injury	(-) OTT (-) NTT Bag-valve mask	Vomiting
F70 (MVA)	RR 32-36, poor chest excursion	(-) NTT Bag-valve mask	Passage unsuccessful
M64 (Fall>8)	traumatic arrest	(-) OTT Bag-valve-mask	Blood in oropharynx (Sub Q air)
M15 (Bike)	RR<10, shallow head injury	(-) NTT Bag-valve mask	Passage unsuccessful
M30 (MCA)	RR=12, shallow head injury	(-) NTT Bag-valve mask	Vomiting
M31 (MCA)	RR=32-34, shallow head injury	(-) OTT (-) NTT Bag-valve mask	Obesity
M32 (MCA)	RR<10, shallow head injury	(-) NTT Bag-valve mask	Blood nares vomiting

Patients less than eight years of age have distinct anatomical differences of their airways. The epiglottis can obstruct visualization of the vocal cords more frequently because it is longer and more rigid. The narrowest portion of the airway in children is below the true vocal cords rather than above the cords as in the adult. Noncuffed tubes are used in these younger patients because of this difference.²⁴ All of the young patients (n=4) in this study were intubated successfully. Knowledge of these anatomical differences contributes to this high success rate of intubation.

Although analysis of variance demonstrated an association between age and success rate of intubation, extrapolation to the general population seemed inadvisable since there were only small numbers of patients in

Table 7
Medications Used for Intubation (n=24)

Succinylcholine	n=19
Vecuranium	n=4
Diazepam	n=4
Morphine sulfate	n=4

the extreme age groups. A limitation of this study is unequal age distribution of trauma patients compared to the population as a whole. In order to form specific conclusions about the very young (age < 8) and the elderly (age > 55) trauma patients with respect to intubation, the analysis should be repeated with larger sample sizes having better representation from these groups. The morbidity and mortality of patients injured over 55 is 10-20% above injury matched younger patients.²⁵ A continued specific focus on these individuals would be helpful in planning treatment strategies.

A trend of increasing physical examination characteristics and decreased success of intubation was documented. The physical examination characteristics selected were a measure of facial injury and corresponded to overall severity of injury when compared to trauma scores. The majority of failed intubations resulted from vomiting or blood in the oropharynx. Copious amounts of vomitus preclude adequate visualization of the vocal cords. The suction apparatus used at the scene of the accident is a portable system which provides less than optimal negative pressure for removal of foreign material (100-200 mmHg for a short duration of time compared to a maximum of 760 mmHg in the emergency department setting). Recognition of this as a factor in increasing the difficulty of scene intubations may lead to earlier performance of the Sellick maneuver or insertion of a nasogastric tube. The Sellick maneuver is compression of the cricoid cartilage and if performed effectively prevents aspiration. The cricoid is the only complete ring of cartilage in the neck and therefore the only location where this maneuver can be effectively performed.¹¹

Because of the presence of combativeness and trismus in many head injured patients, there exists a need for medications (paralytics and sedatives) in scene trauma intubations. When a paralytic is used, it is mandatory to obtain an airway. Although ease of visualizing the cords increases with the use of neuromuscular blockade, the patient is unprotected from aspiration.²⁶ Also, a potentially lethal situation of upper airway obstruction may arise in the paralyzed patient resulting in inadequate oxygenation and ventilation requiring immediate surgical control of the airway. This is not without risks in the multi-injured trauma patient at the scene of an accident.²¹ Only 17.5% of the patients requiring intubation also required the use of medications. All of these patients were successfully intubated. Sedative medications serve a role in creating amnesia, analgesia, muscle relaxation, and may decrease intracranial pressure in the presence of noxious stimuli.²⁷ Their role in scene intubations is yet to be clarified in light of the added risks of hypotension and cardiovascular depression. The nonreversibility of some of the paralytics and sedatives may affect ultimate treat-

ment on arrival to the trauma center. Neurologic examination is no longer reliable. All of these patients are essentially committed to computed tomography even in the absence of head injury. Accurate examination of other body systems (ie, abdominal and skeletal) is not possible with an altered mental status from medications, and additional diagnostic testing may be required. The safety of paralytic and sedative medication for intubation needs to be further evaluated in a larger sample size before their use can be generally recommended.

Table 8
Indications for Medications (n=24)

Trismus	37.5% (n=9)
Combativeness	37.5% (n=9)
Trismus and Combativeness	25.0% (n=6)

It is difficult to measure the actual effect of endotracheal intubation on the outcome of those head injured patients intubated at the scene of the accident. The majority of patients in this study were multiply injured and therefore death could have been due to many variables. Survival of trauma patients aeromedically transported from the scene has been compared to those transported by ground to Hartford Hospital, controlling for injury severity.²⁸ This study eliminated the effect of the trauma center in contributing to increased survival and measured only the aeromedical influence. An increase in survival of 12.1% was noted in the aeromedical group over the ground group. It is difficult to state whether earlier endotracheal intubation contributed to this increase in survival because of the numerous confounding variables. Further work in generating a larger sample size of patients controlling for various factors may answer this important question.

This study describes a population of severely traumatized patients and the success rate of endotracheal intubation. A previous study of prehospital intubations by ground ambulance paramedics also reported a high success rate (96.6%).²⁹ The patient population in the ground paramedic study was predominantly patients with medical conditions (83.7%), unlike this study which consisted of all trauma patients. Both studies demonstrate that prehospital Advanced Life Support teams are able to intubate successfully both high risk medical and trauma patients.

Conclusion

An aeromedical crew comprising a physician, flight nurse, and respiratory therapist can successfully intubate patients at the scene of trauma without early complications. The severe facially injured are difficult groups to intubate. The presence of vomit and blood in the oropharynx are important factors in failed intubations. The elderly patients in this study group were associated with lower success rates of intubation. In patients requiring intubation who display combativeness and trismus as obstacles to securing a controlled airway there may be a role for using medications for muscle relaxation. A high success rate of intubation might be achieved in these patients when the indications and consequences of these medications are carefully evaluated and administered by a highly trained flight crew.

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Suprascapular Nerve Palsy

EUGENE MOSKOWITZ, M.D. AND EVAN S. RASHKOFF, M.D.

ABSTRACT—Isolated traumatic suprascapular nerve palsy without associated fracture is a rare occurrence. Localized segmental muscle atrophy limited to the supraspinatus and infraspinatus muscles associated with weakness in initiating abduction and in external rotation of the shoulder should suggest the diagnosis. Electromyography will confirm the diagnosis by excluding nerve root and brachial plexus involvement with denervation potentials limited to the supraspinatus and infraspinatus muscles.

Introduction

ISOLATED suprascapular nerve palsy is relatively uncommon. It has been associated with fracture of the scapula¹ and entrapment of the nerve in the suprascapular notch.^{2,3,4} Peripheral neuropathies of diabetic or viral origin are rarely limited to involvement of the suprascapular nerve.

The following case report describes an instance of traumatic suprascapular nerve palsy without fracture of the scapula:

A 23-year-old, mental health therapy aide was struck by a pickup truck while crossing the street. He was thrown onto the hood of the truck impacting the posterior aspect of his left shoulder on the windshield and then tossed to the pavement landing on his upper back. He was unconscious when the emergency crew arrived on the scene. While in the ambulance en route to the hospital he regained consciousness and complained of pain in the left shoulder and scapular region. Examination in the hospital emergency department revealed a small laceration of the chin and abrasions in the left scapular region. There were no abnormal neurologic findings. Some tenderness was noted over the left paracervical region. Computed Tomographic scans of the head and cervical spine did not reveal any abnormal findings. He was discharged with a soft cervical collar after an eight-hour period of observation.

During a period of several weeks, the patient noted persistent deep pain and weakness in the left shoulder. An x-ray film of the left shoulder and scapula did not show any fracture. Examination ten weeks following the accident demonstrated localized tenderness over the suprascapular notch, weakness in initiating abduction against resistance and in external rotation of the shoulder with the elbow flexed at ninety degrees. Localized atrophy of the supraspinatus and infraspinatus muscles was evident.

Electromyography of the left upper extremity and cervical paraspinal muscles demonstrated denervation potentials limited to the involved scapular muscles. Isokinetic quantitative muscle testing performed with the Cybex-340 equipment indicated a 39% decrease in strength and a 59% deficit in endurance in external rotation of the left shoulder when compared with the uninvolved right side.

Discussion

The suprascapular nerve emerges from the upper trunk of the brachial plexus (primarily C5 and C6 nerve roots) in the costoclavicular space and runs beneath the trapezius muscle and through the suprascapular notch onto the back of the scapula. Here it gives off a branch to the supraspinatus muscle and passes into the infraspinatus fossa to supply the infraspinatus muscle.⁵ It has no cutaneous sensory distribution but does give off sensory fibers to the acromioclavicular and glenohumeral joints. With paresis of the supraspinatus and infraspinatus muscles, elevation of the arm is not affected since function in the deltoid muscle is intact. Isolated weakness in initiating abduction against resistance and in external rotation of the shoulder localize the lesion. Impaired mobility in the shoulder resulting from paralysis of the spinati was first described many years ago in a classic monograph by Duchenne.⁶

This case emphasizes the need for careful clinical observation and follow-up of patients with injuries to the neck and shoulder without evidence of osseous pathology or obvious soft tissue trauma or disease such as a rotator cuff lesion or bursitis. The occurrence of isolated

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muscle atrophy as a late sequela should suggest the possibility of nerve injury.

Careful muscle testing and documentation can assist in the localization of the lesion. The examiner can pinpoint the lesion, ie, nerve root, plexus, or peripheral nerve, depending on the pattern of muscle weakness (paresis) and atrophy. Electromyography will confirm the diagnosis. Localized muscle atrophy, particularly about the shoulder girdle and scapulothoracic region can be overlooked unless the patient is disrobed and carefully observed both from the front and back with arms at the side and also in flexion and abduction.

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INFLUENZA PREVENTION, 1989-1990

A new trivalent inactivated influenza vaccine is now available for the 1989-1990 influenza season (Morbidity and Mortality Weekly Rep, 38:297, May 5, 1989; Can Med Assoc J, 141:425, Sept 1, 1989). Antigens in this year's vaccine are A/Taiwan/1/86 (H1N1), A/Shanghai/11/87 (H3N2), and B/Yamagata/16/88. The A/Shanghai and B/Yamagata are new strains this year. The vaccine is available in the USA as a split-virus (subvirion) or whole virus preparation from Squibb (*Fluzone*), as a split-virus preparation from Parke-Davis (*Fluogen*) and Wyeth-Ayerst (*Influenza Virus Vaccine, Trivalent*), and as a purified-surface-antigen vaccine from Lederle (*Flu-Imune*). Split-virus or purified-surface-antigen formulations may be less likely to cause adverse reactions, especially in children; whole-virus vaccines may be slightly more antigenic. Vaccine from previous years should not be used.

DOSAGE — A single intramuscular 0.5-ml dose of the vaccine into the deltoid is recommended for adults and children more than three years old, and 0.25 ml in the anterolateral thigh for children six to 35 months old. Children 12 years old or younger should receive only split-virus or purified-surface-antigen vaccine. Children receiving influenza vaccine for the first time should receive two doses, a minimum of four weeks apart.

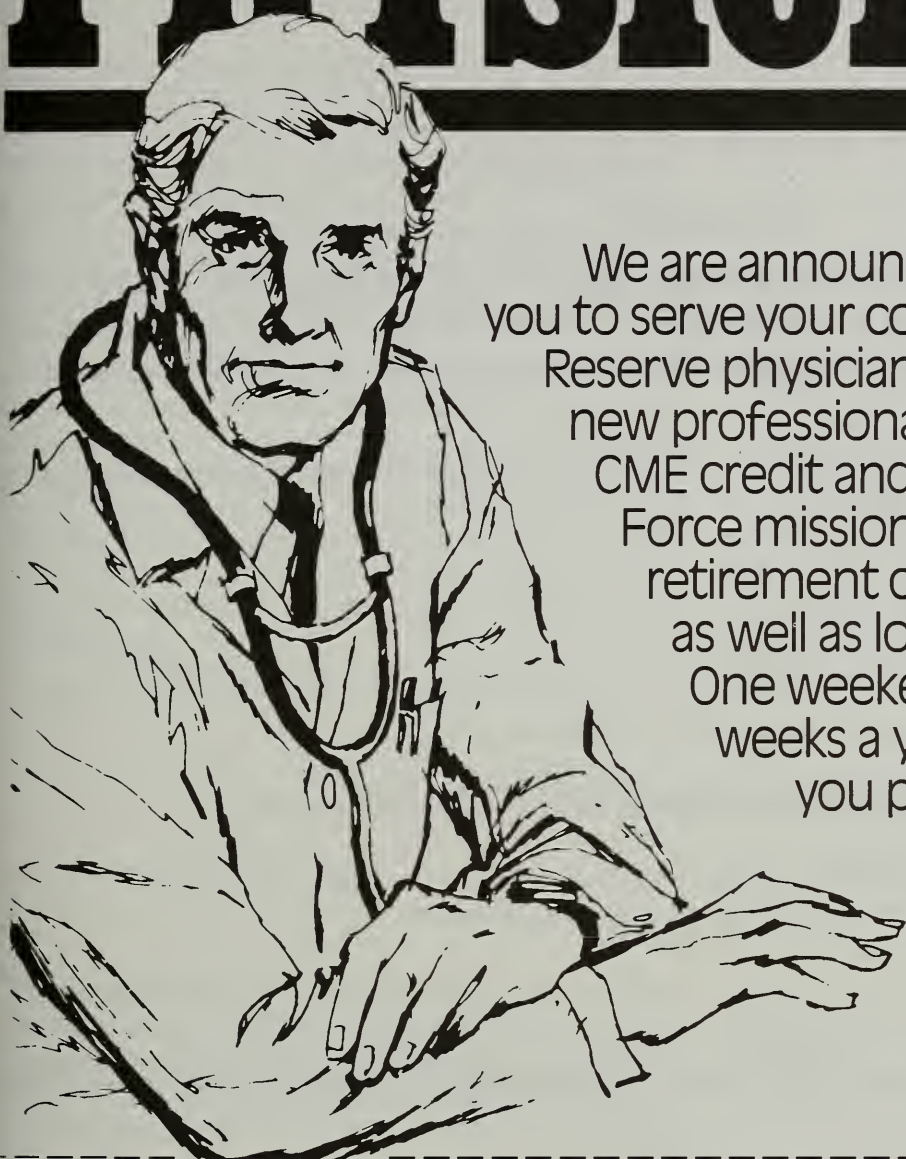
TIMING — Large outbreaks of influenza in the USA usually do not occur before December, reach a peak in January and February, and may continue into the spring. Protection from the vaccine begins about two weeks after injection and generally is thought to last for about six months. Therefore, November may be the best time to give the vaccine. When two doses are needed, the second dose should be given before December.

AMANTADINE — Oral amantadine (*Symmetrel*; and others), 200 mg once daily or 100 mg twice daily, starting before exposure to influenza A and continuing throughout the period of exposure (usually six to eight weeks), can prevent illness in 70% to 90% of adults; it does not prevent infection with influenza B strains. A daily dose of 100 mg may be as effective and causes fewer adverse effects (Morbidity and Mortality Weekly Rep, 37:361, 1988). Amantadine is effective against all strains of type A influenza virus and can be useful for patients who cannot tolerate the vaccine, or as an adjunct to vaccination if an outbreak of influenza A occurs before or less than two weeks after vaccination, or is caused by strains of influenza A not closely related to the antigens in the vaccine (Medical Letter, 30:83, 1988).

CONCLUSION — Trivalent influenza vaccine is recommended especially for high-risk patients, their household contacts, and health care personnel who may come in contact with such patients. Daily prophylaxis with amantadine can also prevent influenza A infection.

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Abstracts: Fourth Annual Research Day

DANBURY HOSPITAL

Introduction

The Fourth Annual Danbury Hospital Research Day was held 10 May 1989. A total of 31 abstracts were submitted, authored or coauthored by 70 individuals. Of note, 11 of these are physicians in private practice, seven are residents, two are nurses, and 11 are technical associates.

Joseph L. Belsky, M.D., FACP, Chief, Endocrinology & Metabolism, Danbury Hospital; Chairman, Research Day Committee.

Prognosis of an Emergency Room Visit Presenting with Right Lower Quadrant Abdominal Pain

DUANE T. FREIER, M.D.

Department of Surgery

A retrospective study was done on 95 consecutive patients upon whom an emergency appendectomy was done at Danbury Hospital. The purpose was to review quality of care using published criteria and identifying factors of predictability of studies currently in practice.

Methods included identification of emergency removal of the appendix in patients seen from January through August 1988; histological determination of the outcome; and documentation of details of management in half of the cases (47).

Undesirable histological outcome (noninflamed or perforated appendices) occurred in 33% of the male and 50% of the female patients. Noninflamed appendices were removed from 4% of the male and 22% of the female patients, a highly acceptable rate by published standards. Rates of perforation were 29% and 28%

respectively, also acceptable but less desirable in terms of potential morbidity.

Detailed review of management showed that 40 operations were clinically justified by objective criteria and seven were not. Total white blood count, presence of immature polymorphonuclear cells, and time delays both as outpatients and inpatients, appeared to be predictive.

Outpatient delays of more than three days and inpatient delays of more than 12 hours were detrimental. Immediate surgical consultation is mandatory in both settings. A total white blood count of over 14,000 or, if less, presence of immature polymorphonuclear cells, strongly indicated that an operation was justified. The practice of not doing differential white blood counts on specimens with less than a total count of 10,000 is not supported by this study.

All authors are at Danbury Hospital in addition to other institutional and departmental affiliations indicated.

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Effect of Tannic Acid Spray on Dust Mite Antigen Levels in Carpet

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Dust mites are a major source of indoor allergen. The use of airtight mattress and pillow encasings together with removal of bedroom carpeting produces a decrease in mite counts and improvement in airway function of dust-allergic asthmatics. Since many dust-allergic patients are unable to remove bedroom carpets and since tannic acid has been shown to inactivate mite allergen *in vitro*, we studied the effect of tannic acid spray on dust mite antigen levels in carpets.

Studies were done in the homes of patients with asthma and positive skin tests to dust mite extracts. A 3% solution of tannic acid was applied with a hand actuated spray pump so that 16 oz. of solution covered approximately 320 sq. ft. of carpet. Dust samples were obtained before and 24 hours after tannic acid treatment and levels of the major dust mite allergens *Der p I* and *Der f I* were measured using a two-site monoclonal antibody radioimmunoassay.

Data were analyzed for homes with pretreatment lev-

els of *Der p I* and *Der f I* >10ug/gm of dust, a level which evidence suggests is a risk factor for allergic asthma:

Carpet	<i>Der p I</i> before/after		<i>Der f I</i> before/after		<i>Der p I</i> + <i>Der f I</i> before/after	
#1	9.5	0.1	4.6	<0.1	14.1	0.1
#2	19.1	<0.1	7.6	<0.1	26.7	<0.1
#3	4.9	2.2	13.4	7.5	18.3	9.7
#4	8.2	<0.1	33.7	2.0	41.9	2.1
#5	13.2	<0.2	4.5	<0.1	17.7	<0.3
#6	4.5	<0.2	19.3	0.3	23.8	0.5

Allergen levels were significantly lower following treatment, p<0.003 by Student's T-test.

Application of 3% tannic acid solution reduces dust mite antigen levels in carpets and may represent an important addition to environmental control measures for allergic asthmatics.

Professor of Medicine (Dr. Platts-Mills), University of Virginia School of Medicine.

Dynamic Scintigraphy for Evaluation of Esophageal Dysfunction

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Departments of Nuclear Medicine and Medicine

Esophageal disorders are widely prevalent in China. Elaborate radiological techniques, manometry, and endoscopy are not commonly available at most centers; therefore, search continues to find simple, inexpensive, and noninvasive modalities to investigate esophageal dysfunction.

Esophageal motility may be affected by several unrelated conditions such as aging, ganglion degeneration, mucosal irritation, neuromuscular conditions, etc. Diffuse spasm may produce retrosternal pain, dysphagia, or both. Conventionally, evaluation of dysphagia is made by barium swallow with cineradiography and esophageal manometry. These procedures however have inherent limitations and recently radionuclide scintigraphy has been introduced for evaluation of esophageal dysfunction.

Twenty-eight patients who underwent esophageal scanning between January and December 1988 were selected for this study. The group ranged in age from 24 to 62 years. There were 10 males and 18 females. Most complained of retrosternal discomfort, dysphagia, or both. Multiple rapid dynamic images were obtained (400 msec.) for 52 sec. after a single swallow of labeled orange juice. Esophageal transit (ET) time of the bolus was also assessed (normal<15 sec.).

Of 28 patients 14 had evidence of diffuse spasm with

normal ET. The adynamic pattern of achalasia, scleroderma, and gastroesophageal reflux were seen in one patient each. The remaining 11 patients had normal patterns of esophageal motility. Of 14 patients, six with spasm showed subsequent improvement; in five symptoms continued in spite of therapy and in three follow-up was not available. Of the 11 patients with negative studies, seven were asymptomatic with or without medication whereas four were lost to follow-up.

In conclusion, scintigraphy provides a simple, noninvasive test for screening of patients suspected of esophageal motility disorder. Though no statistical conclusions can be drawn from this study, the present consensus is that investigation of esophageal dysmotility should commence with barium examination or endoscopy to exclude mechanical obstruction, particularly of malignant etiology. If no abnormalities are detected, a radionuclide study should be used as screening test for motor disorders. If scintigraphy is normal, the chances are that manometry would provide no useful additional information. If scintigraphy is abnormal, manometry may be indicated for precise definition of the disorder.

Associate Professor (Dr. Chen), Nuclear Medicine, Beijing Friendship Hospital; Associate Clinical Professor (Dr. Gupta), Nuclear Medicine, University of Connecticut School of Medicine; Assistant Clinical Professor of Medicine, (Dr. Lichtenstein), Yale University School of Medicine.

The Correlation of Placental and Decidual Histology with Karyotype and Fetal Viability

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Pregnancies (N=143) which were lost prior to 20 weeks gestation were karyotyped and routine sections selected for histologic examination. Villous and decidual characteristics were scored by blinded paired observers. Karyotypes were classified as euploid, viable aneuploid, and nonviable aneuploid. Decidual vasculitis was significantly associated with euploid karyotype and with viable karyotype as compared to nonviable aneuploid karyotype. Increased degrees of hydropic degeneration of the villi was associated with nonviability of karyotype ($p<0.05$). Decidual vasculitis and hydropic changes were not related to each other. In pregnancy losses with viable karyo-

types, 25/73 had decidual vasculitis. We suggest that decidual vasculitis may indicate the presence of subclinical maternal-fetal immunopathology, and that this histologic feature may be useful in targeting patients at risk for recurrent pregnancy loss on an immunologic basis. It may also contribute to the understanding of mechanisms of spontaneous loss of viable aneuploid conceptions.

Assistant Professor of Pathology and Obstetrics and Gynecology (Dr. Salafia), University of Connecticut School of Medicine; Associate Clinical Professor of Obstetrics and Gynecology (Dr. Silberman), Yale University School of Medicine.

DNA Probes for Human Papilloma Virus Typing—Prognostic Implications

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Epidemiologic and demographic evidence of strong correlation between infectious agents and human anogenital carcinoma has been demonstrated. Human papilloma viruses (HPV) are now considered to be the most frequently found organisms in association with cervical, vaginal, and vulvar neoplasia. Certain HPV types (6 and 11) have been mostly associated with condylomas and mild dysplasias. In contrast, HPV types 16 and 18, as well as 31, 33, and 35 are more prevalent in neoplastic lesions.

In infected epithelial cells, viral DNA is found throughout the entire epithelium and HPV virions are seen in the superficial layers. Tissue specimens and smears can be analyzed to detect the presence of HPV DNA.

Recently developed viral DNA *in situ* hybridization techniques allow for accurate detection of the HPV specific type.

Twenty-four of these 40 cases (60%) tested positive for one or more probes. All cases of genital neoplasia, when positive, were associated with HPV types 16-18 and/or 31-33-35.

Eleven out of 16 cases of condylomatous cervicitis show positivity. In six of the 11 cases HPV type 6-11 was demonstrated. In the remaining five cases the specific type was either 16-18 or 31-33-35.

Our results indicate that HPV typing is a useful method to identify a population at risk of developing genital neoplasia.

Interdialytic Symptoms in Hemodialysis Patients Using Polysulfone Membranes Compared with Cupraphane Membranes

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Hemodialysis Department

The purpose of this study was to investigate the difference in interdialytic symptoms of 17 adult patients with end-stage renal disease, 31 to 83 years of age, who had been receiving hemodialysis for at least two months. This group was studied before and after changing from a cupraphane artificial kidney to a polysulfone high-flux membrane. The polysulfone membrane has a larger pore size and is significantly more biocompatible and more efficient than the cupraphane membrane. The study controlled other treatment parameters such as type of machine, type of dialysate, and reuse of dialyzer.

The instrument used was the Hemodialysis Stressor Scale designed by Baldree, Murphy, and Powers (1982). This gives a numerical weight to various stressors, both psychosocial and physiological. A higher score indicates more stress. The test, administered during dialysis treatment, included one pretest and three posttests at one-month intervals. Items evaluated included: length of treatment, decrease in social life, limitation of food, limitation of fluid, interference with job, and physiological aspects including nausea, vomiting, muscle cramps, itching, and stiffness of joints.

There were no significant differences between total scores or physiological subscale scores when the pretest and first posttest scores were compared, or between the pretest and any of the posttest scores over the three month period of testing, related to age or sex. There was a significant decrease ($p < .02$) in total scores and psychosocial subscale scores in those patients who had been on hemodialysis between one and two years. There was also a significant decrease ($p < .03$) in the psychosocial subscale scores of females at the time of the second posttest and a significant decrease ($p < .04$) in psychosocial subscale scores of patients under 60 years of age on the first posttest. All differences favored polysulfone dialysis.

As reimbursement rates decline, dialysis facilities must strive to bring adequate treatment to increasing numbers of patients without increasing costs. One mechanism for providing treatment to more patients is the shortening of treatment times. Four shifts of patients can be handled with little additional staff, in the same amount of space, and with the same number of machines as three shifts. Polysulfone high-flux dialysis is one method of treatment which provides adequate care without increasing patient stress.

Tissue Plasminogen Activator (TPA) in Pulmonary Embolism (PE) and Deep Vein Thrombosis (DVT)

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Department of Medicine

Thrombolytic therapy with streptokinase or urokinase has been shown to resolve PE and DVT faster than heparin, but at substantially increased risk of bleeding. There is preliminary evidence that TPA is considerably safer and even more effective than earlier thrombolytic therapies.

Danbury Hospital is participating in a multicenter randomized controlled study comparing the safety and efficacy of TPA and heparin versus heparin alone in the treatment of PE. Eligible study patients must have well documented PE by high probability V/Q scan or pulmonary angiography and must have low bleeding risk.

Early mortality of PE is probably related to acute pulmonary hypertension with resultant right ventricular dysfunction. Echocardiography can assess cardiac dysfunction in PE patients and can be used to follow efficacy

of thrombolytic therapy. All patients have V/Q scans, echos, and noninvasive venous studies of lower extremities before and after two hour infusions of TPA or heparin.

To date, five patients have been enrolled in the study. One had significant right ventricular dysfunction which improved with TPA therapy within hours. Initial results also indicate that patients treated with TPA had much faster resolution of pulmonary emboli and venous thrombosis than those treated with heparin alone. There has been no evidence of clinically significant bleeding in either the TPA or heparin group.

Associate Clinical Professor of Medicine (Dr. Miller), Yale University School of Medicine, Assistant Clinical Professor of Medicine (Dr. Bier), Albert Einstein College of Medicine.

Quality Control in Performance of Gated Cardiac Dynamic Studies (MUGA SCANS)

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Gated Cardiac Dynamic Imaging (MUGA) studies are commonly performed in nuclear medicine departments throughout the world. Quality control techniques are most often omitted with reasons cited that cardiac phantoms (models) are cumbersome and expensive. The Imaging Resource Committee (IRC) of the Nuclear Medicine Resource Committee (NMRC) of the College of American Pathologists (CAP) has introduced a method to evaluate performance and proficiency using transmission image stimulation (TIS) called the "Danbury Heart." The device mimics a multigated cardiac study in a 45 degree left anterior oblique projection using two metal plates moving in a cyclic fashion to simulate cardiac wall motion and ventricular cavities. The device also produces a signal which serves as the R wave trigger at end diastole. Different models provide various heart rates and arrhythmias, ejection fractions (EF), and wall motion abnormalities (WMA).

Since 1985, 72 randomly selected centers were requested to perform and process studies using three dif-

ferent models described below:

Model	Mean EF	Range	Std Dev	Coeff of Var
Normal EF/rhythm	57%	38%-77%	0.06	11.0%
Low EF/nl rhythm	24%	14%-47%	0.05	21.2%
Normal EF/PVCs	52%	30%-82%	0.10	18.8%

The above data suggest a considerable degree of variance in results, demonstrating a significant degree of interlaboratory variability. The causes of variation are related to different technical procedures, equipment, and computer software employed. Further analysis needs to be performed to determine the specific reasons for this large variability between institutions. The technique used is 2-dimensional and thus cannot reproduce the exact 3-dimensional clinical situation; however, it appears to be a promising inexpensive method for quality control in nuclear medicine laboratories.

Associate Clinical Professor (Dr. Herrera), Pathology, Yale University School of Medicine and New York Medical College; Clinical Professor (Dr. Herrera), Assistant Clinical Professor (Dr. Johns), Associate Clinical Professor (Dr. Gupta), Nuclear Medicine, University of Connecticut School of Medicine.

The Protective Efficacy of Pneumococcal Vaccine

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In an on-going case-control study of the aggregate protective efficacy of pneumococcal vaccine, 660 adults with systemic pneumococcal infection, documented by isolation of *S. pneumoniae* from normally sterile sites (blood, cerebrospinal fluid) from 1984-88, were identified by prospective surveillance of 11 Connecticut hospitals (11% of subjects at Danbury Hospital). Of these patients, 543 (82%) (mean age: 68 years) had an indication for pneumococcal vaccine and were enrolled as cases. For each case, one control, matched to the case by age, hospital, and both type and duration of underlying illness, was randomly selected from suitable potential controls identified from the hospital discharge logs. Antecedent receipt of pneumococcal vaccine was ascertained by contacting all sources of medical care of cases and controls. Isolates of *S. pneumoniae* were serotyped blind to the patient's pneumococcal vaccine status.

Of the infections, 81% and 93% were caused, respectively, by serotypes included in or related to types in the 14 and 23-valent vaccines. Overall, 13% of the cases and 23%

of the controls had received pneumococcal vaccine. The aggregate protective efficacy of pneumococcal vaccine against vaccine or vaccine-related serotypes overall was 61% (95% CI:42%-73%; $P<0.001$). Aggregate protective efficacy was 60% (95% CI:37%-75%; $P<0.001$) for patients with alcoholism or chronic pulmonary, cardiac, or renal disease ($N=341$) and 64% (95% CI:5%-87%; $P<0.05$) for patients >55 years of age without underlying diseases ($N=126$). The protective efficacy of pneumococcal vaccine was specific: a) the protective efficacy against infections with serotypes not included in the vaccine was -11% and b) there was no significant difference between cases (30%) and controls (33%) in the frequency of antecedent immunization with influenza vaccine. We concluded that the aggregate protective efficacy of pneumococcal vaccine against systemic pneumococcal infections is substantial.

Assistant Professor Pediatrics and Epidemiology (Dr. Shapiro), Associate Research Scientist, Pediatrics (Dr. Berg), Yale University School of Medicine.

Adjustable Suture Strabismus Surgery

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Since the introduction of adjustable suture strabismus surgery in 1976, its acceptance has been slow. Critics suggest an increased incidence of complications without an increase in surgical success.

This paper identifies surgical complications due to muscle surgery and to adjustable suture technique. Ocular alignment drift during healing is identified and quantified. Success rates are defined and compared to those reported in the literature.

Results of 771 consecutive cases reveal a complication rate due to adjustable suture technique of 2.7%. Only one-third of these required reoperation. Complications included: suture pulling through the sclera, suture breakage, and slipped muscle. Postoperative drift was dependent on the preoperative diagnosis. Postoperative suture

adjustment to the optimal position (to account for drift during healing) increased surgical success by an average of 8.4%. Overall surgical success is increased by 10% to 20% by using adjustable sutures when compared to success reported in the literature for standard strabismus surgery.

In summary, postoperative drift must be included in surgical decision making, there are few serious complications from the adjustable suture technique, and surgical success is greatly enhanced using the adjustable suture technique.

Assistant Clinical Professor (Dr. Eggers), Clinical Professor (Dr. Knapp), Ophthalmology, Columbia College of Physicians and Surgeons.

Kawasaki Syndrome: A Paradigm of Efficacious Intervention with Intravenous Gammaglobulin

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Department of Pediatrics

Kawasaki Syndrome (KS) or mucocutaneous lymph node syndrome is an acute vasculitic illness of infancy and childhood characterized by (1) fever; (2) nonexudative conjunctivitis; (3) injected oral mucosa, fissured lips, or strawberry tongue; (4) palm and sole erythema, edema, or desquamation; (5) polymorphous rash, and (6) cervical lymphadenopathy. Leucocytosis, thrombocytosis, and elevated erythrocyte sedimentation rate (ESR) are noted in these patients. In the absence of intervention, about 20% of the patients will develop coronary-artery aneurysms or ectasia with subsequent susceptibility to complications of myocardial infarction, sudden death, or chronic coronary-artery insufficiency.

Consecutive cases of KS admitted to the Danbury Hospital between 1 January 1985 and 31 December 1988 were studied. During these four years, only two of the 11 cases were admitted in the first two years. Treated with supportive therapy only, one of these two patients developed extensive aneurysmal lesions in both left and right coronary arteries. Nine cases of KS were admitted for treatment with intravenous gammaglobulin at 400

mg/Kg/day X 5 days during the last two years of the study. These patients included five boys and four girls with their mean age being 5.1 ± 2.4 years. In addition to the fulfillment of clinical diagnostic criteria, these cases also showed leukocytosis of $12.1 \pm 3.4 \times 1000/\text{cmm}$ and elevated ESR of 68 ± 36 mm/hour. In this study we were able to document additional laboratory abnormalities in KS patients: hyponatremia of 133 ± 3 mEq/liter, hemoglobin of 10.3 ± 1.1 g/dl, and hematocrit of $33.1 \pm 3.5\%$. Defervescence was noted in all patients shortly following the initiation of the first dose of gammaglobulin. None of these nine patients developed coronary lesions as assessed by repeated echocardiograms.

This study confirms the efficacy of intervention with intravenous gammaglobulin in the prevention of coronary lesions developing in patients with KS. Furthermore, the need to begin treatment prior to the development of coronary lesions emphasizes the importance of making an early diagnosis of the syndrome.

Associate Clinical Professor, Department of Pediatrics, Yale University School of Medicine.

Microtubule Disassembly: A Possible Mechanism of Cyclosporine A Toxicity

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Cyclosporine A(CsA), a lipophilic cyclic undecapeptide, is an immunosuppressive agent used in organ transplantation. In addition to its immunosuppressive action, CsA has cytotoxic effects on renal, hepatic, and neural tissues. Although the immunosuppressive action of CsA has been attributed to CsA-calmodulin binding and consequent inhibition of calmodulin dependent protein kinases, the mechanism/s of the cytotoxic actions of CsA remain unclear. We describe here a possible mechanism for its cytotoxic actions. Human umbilical vein endothelial (HUV), epithelial (A549), adenocarcinoma (SKHEP1), fibroblast (SKP5), and bovine pulmonary artery endothelial (BPAE) cells were cultured in complete media, serum-deprived for 24-36 hours, and exposed to CsA (10^{-9} - 10^{-4} M). Cells were fixed and processed for immunofluorescence localization of microtubules (MTs) with a monoclonal antibody to alpha tubulin. BPAE and

SKP5 cell monolayers were also subjected to experimental wounding and monitored for centrosomal orientation and cell migration responses. We found that CsA induced a rapid (within 5 min) disassembly of MTs *in situ*. The effect was concentration-dependent with the maximal effect being observed at 10 μ M. MT disassembly persisted for 4-5 hours after removal of CsA. CsA also partially blocked serum-induced centrosomal orientation and cell migration responses to wounding. CsA-induced MT disassembly was blunted by interleukin 1 and gamma interferon but not by 10% calf serum, insulin-like growth factor I, or the phorbol ester TPA. This novel action of CsA could be an important mechanism of CsA's clinical toxicity.

Clinical Assistant Professor (Dr. Mascardo); Adjunct Assistant Professor of Medicine (Dr. Barton), University of Connecticut School of Medicine.

Cytogenetic Findings in Products of Conception: Results from Danbury Hospital, January to December 1988

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CLAUDIA WALSH, B.A.

Department of Laboratory Medicine

Population studies have shown that one in 13 conceptions is chromosomally abnormal. Trisomy (47 chromosomes) accounts for about half of these abnormalities. Polyploidy is the next significant chromosomal cause for loss: triploidy ($3N=69$ chromosomes) represents about 17% and tetraploidy ($4N=92$) about 6% of these abnormal abortuses. The single most common chromosomal abnormality (18%) is 45,X (Turner's syndrome: *Genetics in Medicine*, 4th Ed, Thompson and Thompson 1986, p 127).

During the 12 month period of 1988, 99 products of conception (POC) were received for cytogenetic evaluation. Of these, 14% failed to grow and 4% had to be discarded before growth because of contamination. The results of the remaining specimens were reviewed in order to see if there was any variation from the norm.

There were 39 abnormal and 42 normal karyotypes. Frequencies of the different categories were similar to what was expected regarding the percentage of trisomies and polyploids. There were two findings which were

different from the norm. The incidence of 45,X was slightly higher than expected: 23% v 18%. The types of chromosomal trisomies which were found were different from those usually found, except for trisomy 16 (15.0% v 16.4%), trisomy 21 (5.0% v 4.7%), and trisomy 22 (7.5% v 5.7%). The commonly found trisomies of 14, 15, and 18 were not found in our POC samples, except for one specimen which had a double trisomy (15 and 20). In addition there was one POC with a ring chromosome (unidentified). There was one case of a monosomy for chromosome 21. This existed in a mosaic state, that is, not all the cells were missing the chromosome. Mosaicism was present in six of the POCs.

Although the number of POC specimens that were studied this past year was small, it can be pooled with the data found during the previous four years as well as data which we anticipate for the future. Thus, we will be able to see any trends which may be significantly different from published population studies.

Fetal Growth Patterns in Preterm Delivery: Correlations with Placental Pathology

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Departments of Laboratory Medicine and Obstetrics and Gynecology

Of 477 consecutive preterm deliveries, there were 25 unexplained stillbirths, 27 cases of preeclampsia, 20 cases of placenta previa, and 405 cases of idiopathic preterm labor. Placental pathology, including acute (ascending) inflammation, placental infarction, intervillous thrombosis, chronic villitis, and hemorrhagic endovasculitis was studied in relation to clinical indications and neonatal growth measures. Significant associations included: (1) The incidences of placental lesions differed among the various groups. Acute inflammation was more frequent among cases of idiopathic preterm labor, while placental infarction and chronic villitis were more frequent among preeclamptics. Hemorrhagic endovasculitis was more frequent among cases of stillbirth or preeclampsia. (2) Acute inflammation was associated with normal growth for dates, but decreased birthweight and length for placental weight ($p < 0.05$). (3) Placental weight, infarction,

and chronic villitis showed different associations with fetal growth depending upon the clinical circumstances. Among preeclamptics, placental weight and infarction were consistently related to decreased birthweight and length for dates ($p < 0.05$), but chronic villitis was not. In idiopathic preterm labor, chronic villitis was related to decreased birthweight, length and head circumference for dates ($p < 0.05$). Placental infarction was related to decreased birthweight for dates only. The placental lesions' effects were independent of maternal factors. In placenta previa and stillbirth, placental pathology was not associated with decreased fetal growth. Hemorrhagic endovasculitis and intervillous thrombosis were not associated with decreased fetal growth.

Assistant Professor of Pathology and Obstetrics and Gynecology (Dr. Salafia), University of Connecticut School of Medicine; Associate Clinical Professor of Obstetrics and Gynecology (Dr. Silberman), Yale University School of Medicine.

Evaluation of Immunoinhibition (INH) and Immunoprecipitation (IPPT) Methods for the Measurement of Creatine Kinase-MB Activity in Serum

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Department of Laboratory Medicine

Serial measurements of creatine kinase (CK) and its "cardiac" isoenzyme, creatine kinase-MB (CK-MB), provide valuable diagnostic information in the evaluation of patients with suspected acute myocardial infarction (AMI). At the Danbury Hospital clinical chemistry laboratory, CK-MB has traditionally been analyzed by a procedure involving separation of CK isoenzymes by agarose gel electrophoresis (AGE), fluorescent visualization of the isoenzyme bands, and reporting CK-MB as "positive," "trace," or "negative." The AGE procedure is relatively sensitive and extremely specific for CK-MB and also allows detection of the CK-BB isoenzyme and "atypical" (macro) forms of CK. However, it is time consuming, labor intensive, and not suitable for the analysis of STAT specimens. Furthermore, interpretation of AGE results is somewhat subjective and the results are not quantitative. A quantitative assay capable of providing CK-MB results on demand is desirable for the timely diagnosis and disposition of patients with suspected AMI, for monitoring patients with an established diagnosis of AMI, and for assessing the degree of

reperfusion in patients treated with thrombolytic agents.

With this goal, we evaluated the Kodak EKTACHEM immunoinhibition (INH) and Roche Diagnostics immunoprecipitation (IPPT) methods for CK-MB. Both methods showed excellent agreement with each other (97%) and with the AGE method (97% for INH and 99% for IPPT) in classifying patients as positive or negative for AMI on 190 successive serum samples submitted for CK-MB. We found the automated Kodak INH assay to be precise, sensitive, rapid, easy to perform, and cost effective. The INH assay is not entirely specific for CK-MB and is prone to interference by CK-BB and macro CK types 1 and 2; however, it is an effective front-line CK-MB measurement if utilized properly. Serial measurements of both total CK and CK-MB activity must always be obtained and considered in combination with the CK-MB activity expressed as a percentage of the total CK activity, ie, $\%MB = (CK-MB / \text{total CK}) \times 100$, using carefully selected cut-off values. For a diagnosis of AMI, we found that the *peak* values for total CK, CK-MB, and $\%MB$ should be greater than or equal to 100

U/L, 15 U/L, and 5%, respectively. A small percentage of patients with AMI had peak %MB values below the 5% cut-off. For these patients, total CK levels were typically greater than 1000 U/L and the %MB cut-off appeared to be closer to 2%. When the %MB by INH exceeds 15%, CK-BB or an atypical form of CK may be present, and the CK-MB result should be confirmed by a more specific method. We found the Roche Diagnostics IPPT assay to be very specific for CK-MB. Although we found this technique to be more labor intensive and too expensive for use as a front-line CK-MB assay, it is well

suited for use as a confirmatory assay when the %MB by INH exceeds the 15% limit. When CK-MB results by the IPPT method did not confirm those obtained by the INH assay, the latter results were always higher and electrophoresis was useful in identifying the interferent in the INH assay as CK-BB or as macro CK (type 1 or 2). During this study, one case of each of the above was found and will be presented.

Visiting Scientist (Dr. Huang) Beijing Friendship Hospital, Beijing, China.

The Dipeptide Succinylleucylagmatine (SLA) Stimulates Directed Cell Migration by Modulating Protein Kinase C Activity, and Enhances Arterial Intimal Recovery from Injury

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To clarify the mechanism of the chemokinetic action of the protease inhibitor, E-64, on bovine arterial endothelial (BAE) cell monolayers subjected to wounding (*JPET* 244:361-67, 1988), we synthesized SLA; N-(N-succinyl-L-leucyl) agmatine, an analogue of E-64 devoid of any protease inhibitory action. Using a BAE monolayer model of cell polarization and migration responses to wounding, we observed that SLA (1-100 μ M) induced a rapid (<1 min) polarization response in cells at the edge of the wound, and a significant locomotor response one to three hours after wounding. Diluent-treated control cells showed no significant response. The phorbol ester 12-O-tetradecanoyl-phorbol-13-acetate (TPA) mimicked the SLA effect, and the protein kinase C (PKC) inhibitors tamoxifen, sphingosine, and H7 blocked it; these results indicated that the action of SLA was mediated by PKC activation. SLA (100 μ M) induced a rapid and transient one to five minutes translocation of PKC activ-

ity from the cytosol to the membrane fraction of the BAE homogenate. When added to ^{32} P-labeled cells, SLA induced the phosphorylation of four proteins (23.4, 25.4, 28.5 and 36.5 kDa) as shown by 1- and 2-D PAGE and autoradiography. TPA-treated cells also exhibited PKC activity translocation, and phosphorylation of the 23.4 and 36.5 kDa proteins. Thus the SLA effect is partly mediated by PKC activation. To determine if SLA could stimulate vascular endothelial cell response to injury, we induced carotid artery intimal denudation with nitrogen gas, and observed the recovery of the intimal lining one to ten days after injury in rats treated with diluent or SLA (60 mg/KG i.p., Q.D.). We observed a more rapid regrowth of the denuded intima in SLA-treated rats. In conclusion, SLA apparently stimulates the wound healing process.

Clinical Assistant Professor (Dr. Mascardo), Medicine, University of Connecticut School of Medicine.

Failure of Once-Daily Penicillin V Therapy for Streptococcal Pharyngitis

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To determine if a single daily dose of penicillin V would be effective in the treatment of group A beta-hemolytic streptococcal (GABHS) pharyngitis, 154 patients with GABHS pharyngitis were randomly assigned to receive 750 mg of penicillin V once daily for 10 days or 250 mg of penicillin V three times daily for 10 days. The two regimens were comparable in their ability to eradicate GABHS from the upper respiratory tract in 18 to 24 hours and in their impact on the clinical course of the

disease. However, a bacteriologic treatment failure occurred in six (8%) of the 75 patients in the three-times-daily group and in 16 (22%) of the 74 patients in the once-daily group. These findings support the current recommendation that penicillin V be given in two or more doses for a full 10 days for the treatment of GABHS pharyngitis.

Clinical Professor (Dr. Randolph, Dr. Feder), Associate Professor (Dr. Gerber), Pediatrics; Clinical Professor (Dr. Feder), Family Practice, University of Connecticut School of Medicine; Professor of Pediatrics (Dr. Kaplan), University of Minnesota Clinics.

The Distribution of Intercellular Adhesion Molecule Within Decidua and Placenta and Gestational Age-Associated Changes

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Intercellular adhesion molecule (ICAM-1) is a ligand of leukocyte functional antigen (LFA-1) present on many cells, including monocyte/macrophages. It is considered to play an important role in the induction and/or maintenance of inflammatory responses, permitting leukocyte adhesion. Its expression is inducible in epithelial cells exposed to antigenic stimuli (preceding expression of histocompatible locus antigen, HLA D-DR) and is maturation dependent in certain cell lines. The distribution of ICAM-1 in decidua and placenta was evaluated using monoclonal antibodies and peroxidase-antiperoxidase immunohistochemistry. In decidua of first and third trimesters, scattered ICAM-1 (+) cells were observed. In placentas of first and third trimesters, all types of trophoblast were ICAM-1(-). Prior to 10 weeks gesta-

tion, the villous stroma was uniformly ICAM-1 and HLA D-DR(-). Beginning in the chorionic plate at approximately 10 weeks, scattered ICAM-1 (+) stromal cells were observed, while stromal cells of the terminal villi were ICAM-1 (-). By 14-16 weeks, approximately 40%-50% of the terminal villous stromal cells were ICAM-1 (+). This parallels the 40-50% of the villous stromal cells which share other immunohistochemical markers (such as EB-11) with monocyte/macrophages. The lack of functional maturation of the villous stromal macrophage may explain the rarity of chronic villitis early in gestation.

Assistant Professor of Pathology and Obstetrics and Gynecology
(Dr. Salafia), University of Connecticut School of Medicine.

Placental Pathology in Preterm Deliveries Identified by Abnormal Scores on the Preterm Scoring Index (PSI)

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A preterm Scoring Index (PSI) has been in use at Danbury Hospital since 1987. It has been demonstrated to identify patients at increased risk of preterm delivery. The factors considered include socioeconomic, infectious, medical, and uterine structural attributes. In a preliminary analysis, we examined the placental pathology associated with 10 cases of preterm delivery when a high PSI was present compared to 23 cases of preterm delivery in which a low (normal) PSI was obtained. No significant differences in the gestational age at delivery, placental weight, and presence of placental pathology, including markers of acute (ascending) infection, placental infarction, chronic villitis, and hemorrhagic endovascularitis was observed between preterms with high v low PSI. Risk factors were examined in the two groups. Only the history of a past preterm delivery or second trimester loss was significantly related to high PSI (8 of 10 v 0 of

23). Six of the eight cases with history of past preterm or second trimester delivery had placental information available for the earlier delivery. In five of six cases, the placental pathology of the two deliveries was identical, eg, successive cases of acute ascending infection, or repeated placental vascular pathology. This study is presently being expanded. Our preliminary observations suggest that the placental pathology associated with past preterm delivery is the best predictor for the pathology which will accompany future preterm pregnancies. We suggest that targeting of therapeutic interventions would benefit from application of placental pathology.

Assistant Professor of Pathology and Obstetrics and Gynecology
(Dr. Salafia), University of Connecticut School of Medicine; Associate
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Maternal and Placental Characteristics of Growth-Retarded and Nongrowth Retarded Infants at Term

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We had 147 cases with birth weight (BW) below the 10th percentile at term (intrauterine growth-retarded, IUGR) to compare with 123 gestational age-matched cases with BW greater than the 10th percentile (non-IUGR). Prepregnancy weight and mean maternal weight gain during pregnancy of IUGR cases were significantly less than in non-IUGR cases. IUGR cases included 45 of 67 (67%) cases with chronic villitis (31% of IUGR cases), 41 of 63 cases (65%) with placental infarction (28% of IUGR cases), and 20 of 26 cases (77%) with hemorrhagic endovasculitis (HEV) (14% of IUGR cases). Chronic villitis, placental infarction and HEV were related to low BW ($p < 0.05$) (mean BW differences, IUGR v non-IUGR, -240 g, -370 g, and -380 g respectively). Only placental infarction was related to decreased birth length ($p < 0.001$). Chronic villitis, placental infarction, and HEV were associated with decreased placental weight ($p < 0.05$). The effects of placental infarction on BW were independent of placental weight; chronic villitis was related

to low BW due to an association with smaller placentas. Low ponderal index (weight/length³ x 100) cases showed a significantly increased rate of chronic villitis. Placental lesions were not related to maternal racial, socioeconomic, or medical factors. We suggest: (1) subclinical placental pathology is significantly associated with growth failure in our experience at Danbury Hospital; (2) different placental lesions show different patterns of related growth failure; (3) chronic villitis indicates congenital viral infection and should show varied fetal effects, depending upon the gestational age of infection. The late onset (low ponderal index) pattern of IUGR suggests an unusual preponderance of third trimester infections, or a different mechanism of fetal compromise.

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Placental Pathology of Preterm Deliveries: Acute Inflammation, Placental Vascular Disease, and Chronic Placental Inflammation

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Department of Laboratory Medicine and Obstetrics and Gynecology

Placentas from 477 pregnancies that were delivered between 20 and 36 weeks of gestation were examined for the presence of placental pathology. Higher grades of severity of maternal inflammatory response and umbilical vasculitis were significantly more frequent at the earliest gestational ages (20-28 weeks). Placental vascular disease (infarction or intervillous thrombosis) and chronic placental inflammation (chronic villitis and hemorrhagic endovasculitis) were more frequently seen among preterms than in a group of unselected term deliveries. The presence of acute inflammation was classified as "equivalent to that seen in 95% of term deliveries" (based on a data set examined in this laboratory). The presence of placental vascular or chronic inflammatory lesions were significantly more frequent among pre-

terms without "excess" acute inflammation. The placentas in such cases were also smaller than in cases of acute inflammation. Placental vascular and chronic inflammatory lesions may be the result of chronic congenital viral infection or maternal fetal immunopathology. In patients without an excess of acute inflammation to provide a stimulus for the premature onset of labor, we suggest that chronic inflammatory stimuli may result from viral or fetal antigens, and promote preterm labor by pathways similar to those proposed for acute intrauterine bacterial infections.

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Immunohistochemical Detection of Ceruloplasmin in Thyroid Nodules

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Departments of Laboratory Medicine and Medicine

Distinguishing malignant from benign thyroid nodules by fine needle aspiration cytology is difficult. Sensitivity and specificity rates of no higher than 85% and 90%, respectively, are achievable in the best of hands. To improve these rates, various groups have attempted, without success, to identify tumor markers that are detectable in vitro by immunohistochemical techniques. One group has reported success using a monoclonal antibody to the copper-binding protein, ceruloplasmin: follicular and papillary carcinomas but not follicular adenomas stained for this protein.

We attempted to reproduce the above results using an anticerculoplasmin monoclonal antibody preparation (1:75 dilution) and representative paraffin-embedded tissue sections from 43 benign and malignant thyroid nodules. Cases were obtained from the Danbury Hospi-

tal Surgical Pathology files from 1984 to 1988.

Of the 43 cases studied, significant positive staining for ceruloplasmin was demonstrated in 43% (3/7) of nodular goiters, 53% (9/17) of follicular adenomas, 25% (1/4) of follicular and Hurthle cell carcinomas, and 100% (9/9) of papillary carcinomas. None of three colloid nodules, two inflammatory lesions, or one primary malignant lymphoma stained for ceruloplasmin.

We conclude that immunohistochemical detection of ceruloplasmin is not helpful in distinguishing benign from malignant thyroid nodules and would not, therefore, enhance the diagnostic accuracy of fine needle aspiration cytology.

Clinical Professor of Medicine (Dr. Belsky), Yale University School of Medicine.

Retinal Pigment Epithelium Transplantation in the RCS Rat

VINCENT S. REPPUCCI, M.D., PETER GOURAS, M.D., ROBERT LOPEZ, M.D.,

MARIELLE BRITTIS, M.D., BRENDAN SULLIVAN

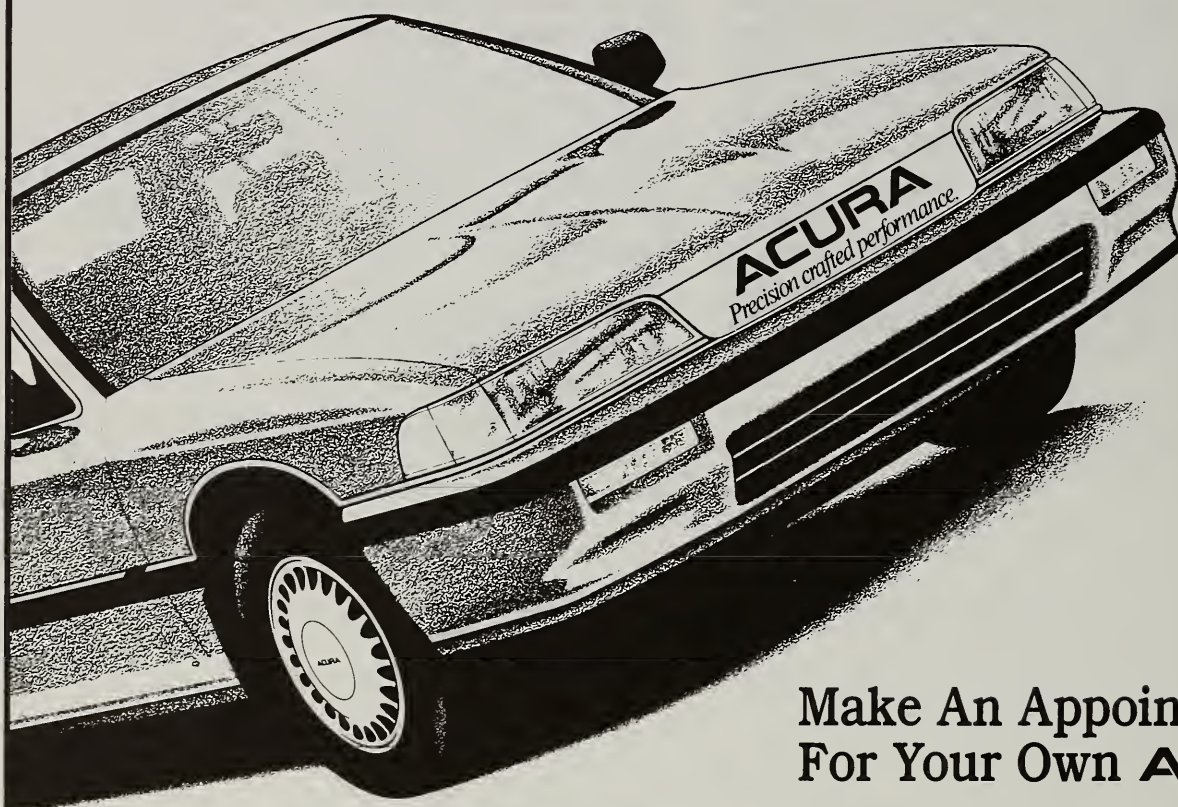
Department of Surgery, Danbury Hospital, and Department of Ophthalmology, Columbia University, College of Physicians and Surgeons

A closed eye method has been developed to replace the retinal pigment epithelium (RPE) of albino RCS rats with inherited retinal dystrophy with normal RPE cells from a congenic pigmented strain. The eye is entered through an equatorial stab incision with a glass micropipette having an external tip diameter of 75-100 μ m. The pipette is filled with a suspension of dissociated, previously cultured and pigmented RPE cells from the normal strain. Under direct visualization using a hand held corneal contact lens and surgical microscopy, the pipette is guided through the vitreous to the retina on the opposite side of the eye. A microinfusion pump creates a jet stream of fluid producing a retinal hole, removal of host RPE cells from Bruch's membrane, and a bleb

detachment by the subretinal infusion of the transplant RPE suspension. Within 12-24 hours the neurosensory retina reattaches and ophthalmoscopy of the albino host confirms the subretinal location of the pigmented transplant RPE cells. In a one-month-old rat this provides a viable mixture of normal and dystrophic RPE cells upon Bruch's membrane to be in apposition with photoreceptor outer segments. This closed eye method allows for an animal model to study the role of RPE transplantation in the treatment of inherited retinal dystrophies.

Clinical Instructor (Dr. Reppucci), Cornell University College of Medicine, Professor (Dr. Gouras), Clinical Instructor (Dr. Lopez), Columbia College of Physicians and Surgeons.

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Case Report: Bronchogenic Cyst Causing Ventilation/Perfusion Mismatch on Lung Scan

FATIMA YOOSUFANI, M.D., WILLIAM JOHNS, M.D., TIZIANA PANIAGUA, M.D.,
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Departments of Nuclear Medicine and Medicine

A 27-year-old woman presented with a one-week history of pleuritic chest pain and shortness of breath. She had been taking oral contraceptives for several years and had no history of lung disease. Her physical examination was unremarkable except for mild tenderness of the left calf. The arterial blood gases were abnormal with pH 7.45, pCO₂ 28 and pO₂ 81. A chest film showed relative oligemia in the right lung field (+Westermack's sign) and EKG had an SIQ3 pattern. A lung perfusion scan demonstrated generalized decreased perfusion to the right lung and a portion of the left upper lobe. Ventilation was normal. This was interpreted as indicating a high probability for pulmonary embolism. The patient was admitted and heparin was administered.

A subsequent Doppler study of the lower extremities was negative for deep vein thrombosis. Pulmonary angiography demonstrated a "questionable" clot in the right main pulmonary artery.

Chest computed tomographic scan showed a hypodense mass in the middle mediastinum below the bifurcation of the trachea. This compressed the right main pulmonary artery and was consistent with the presence of a bronchogenic cyst. The patient was discharged and

is to be evaluated by a thoracic surgeon for possible resection of the cyst.

Bronchogenic cysts are congenital lesions lined with ciliated columnar epithelium and result from abnormal branching of the tracheobronchial tree during its embryologic development. They may become very large in adults without causing symptoms. Unless they become infected, they do not communicate with the tracheobronchial tree.

Unilateral absence of ventilation and perfusion (V/Q match) due to the presence of a bronchogenic cyst has previously been reported. This is the first reported case of normal ventilation with significant perfusion defects (V/Q mismatch) as a result of such a cyst, and may be added to the list of possible causes of false positive "high probability" lung scans. Other possible causes include bronchogenic carcinoma, pulmonary artery atresia/congenital heart disease, aortic aneurysm, radiation fibrosis, Takayasu's arteritis, and Swyer-James Syndrome.

Assistant Clinical Professor (Dr. Johns), Nuclear Medicine, University of Connecticut School of Medicine; Associate Clinical Professor (Dr. Miller), Medicine, Yale University School of Medicine.

The Prevention of Postoperative Nausea in Cataract Surgery

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Department of Surgery (Ophthalmology)

Postoperative nausea and vomiting is a potential source of wound dehiscence, infection, intraocular lens dislocation, hemorrhage, and wound leaks. Traditionally, high postoperative intraocular pressure was thought to be the major cause of nausea. A review of 325 cases undergoing cataract surgery (manual extracapsular technique and phacoemulsification) identifies new causes of postoperative nausea.

Significantly, the use of Miochol (acetylcholine) is associated with a lower rate of nausea than Miostat (carbachol). High intraocular pressure is seen in both groups postoperatively, but is not present in all cases of

Miostat-induced nausea. Miostat-induced nausea is a new clinical entity which is characterized by epigastric discomfort, myalgias, and weakness.

Neither Miochol or Miostat were found significantly to lower the intraocular pressure in postoperative patients. However, the use of a carbonic anhydrase inhibitor (Diamox sequel) significantly lowered the intraocular pressure. Furthermore, the use of a post-lens insertion lavage also significantly lowered the intraocular pressure.

In summary, the use of Miochol, post-lens lavage, and one Diamox sequel significantly lowers the incidence of postoperative nausea in cataract surgery.

Plaquenil Therapy for Corneal Edema: A Case Report

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Department of Surgery (Ophthalmology)

The symptomatic treatment of corneal edema has been limited to the use of hypertonic solutions, heated air, and corneal transplant. This abstract reports the use of plaquenil in identical twins with Fuch's Dystrophy.

Twins, age 42, presented with a history of mixed connective tissue disease in 1985, and with the complaint of blurred vision in the morning. Neither twin was taking plaquenil. Both were noted to have 2-3+ guttata and mild corneal edema. They were started on a regimen of hypertonic saline drops and the use of a blow drier in the morning. Over the next two years they both did well with vision in the 20/25 range.

In early 1987 one twin (twin 1) was noted to have significantly more corneal edema than her sister (twin 2). Upon questioning, twin 2 reported being on plaquenil for the last six months. Twin 1 was not using plaquenil. As a result, twin 1 was started on plaquenil with an improvement of her vision from 20/60 range to the 20/25 range after three to four weeks of therapy with plaquenil. Both twins have continued to take plaquenil.

Subsequently, plaquenil has been used on other patients with similar encouraging results. A double-blind study is now indicated.

Effects of Lithium Therapy on Renal and Parathyroid Functions

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Clinical Laboratory and Department of Medicine, Fairfield Hills Hospital, and Department of Medicine, Danbury Hospital

Lithium carbonate is widely used for treatment of bipolar disorders. A wide range of metabolic effects related to chronic lithium toxicity have been reported including hypercalcemia caused by lithium induced parathyroid dysfunction. Some studies have also shown that beta-2 microglobulin (b-2m) correlates better with glomerular filtration rate than serum level of creatinine and, therefore, monitoring of b-2m in patients on lithium carbonate therapy may provide a sensitive indicator to detect early derangement of lithium related renal dysfunction.

We studied 52 patients on long-term lithium carbonate therapy selected at random to assess the effects of chronic therapy on serum creatinine, b-2m and calcium levels. The group consisted of 18 females and 34 males with an age range of 22 to 57 years. Daily doses of lithium carbonate ranged from 300-1,800 mg/day with an average daily dose of 900 mg. Duration of treatment ranged from three months to 180 months with an average of 32 months. Levels of serum calcium, phosphorus, albumin, sodium, glucose, blood urea, and serum creatinine were obtained in all patients. Serum calcium was normal in all patients with a range of 8.5-10.5 mg/dl (normal 8-10.5). Serum creatinine ranged from 0.7 to 2 mg/dl (normal 0.6-1.5). Serum b-2m was performed in 12 patients and urinary creatinine clearance was performed in 10 patients. In two out of three patients with elevated serum creati-

nine level (more than 1.6), the b-2m was increased; whereas, in one patient with serum creatinine of 1.6, the b-2m was normal. (creatinine clearance was decreased in all three patients with elevated serum creatinine levels. It was decreased in three other patients in whom serum creatinine level was at the upper limits of normal and, in two other patients with normal serum creatinine. B-2m was normal in all patients with normal serum creatinine. Overall, there was good correlation between serum creatinine, urinary creatinine clearance, and b-2m levels.

In conclusion: (1) There was no evidence of lithium associated hypercalcemia or hyperparathyroidism in this group of patients. (2) Only a small fraction (5.7%) of the patients on lithium carbonate therapy were found to have mildly deranged glomerular renal functions. (3) There was good correlation between serum b-2m levels, serum creatinine, and urinary creatinine clearance. (4) Creatinine clearance did not appear to be helpful in assessing glomerular filtration rate in psychiatric patients because in a large number of cases with normal serum creatinine it was found to be abnormal due to various factors. (5) Long term longitudinal studies with serial assessment of metabolic functions would be needed in a large number of such patients to draw any firm conclusions about the prevalence of metabolic effects from long term lithium carbonate therapy.

Clinical Professor (Dr. Belsky), Medicine, Yale University School of Medicine.

The Added Value of High Density Lipoprotein at Initial Cholesterol Screenings

JOSEPH BUCHMAN, M.D.

Department of Medicine

Approximately 5,000 cholesterol screenings have been accomplished in our area through the Preventive Cardiology Program. A report of an elevated level may produce significant anxiety. To confirm the value of testing for high density lipoprotein levels (HDL) with cholesterol in guiding therapy and allaying subject anxiety, two groups were screened, one for cholesterol alone; another for HDL plus cholesterol. Seventy-five school teachers in Danbury had screening cholesterol tests only, and 50 teachers in Ridgefield had HDL and cholesterol tested.

HDL cholesterol testing requires (a) a four-hour fast, (b) a venipuncture, (c) has the potential for a second added laboratory error, and (d) an additional cost.

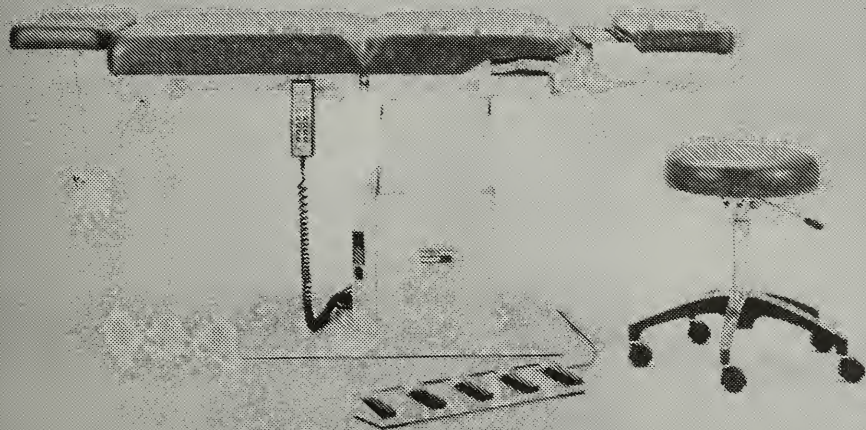
Seventy-five percent of the teachers had elevated cholesterol and a second determination was necessary by national cholesterol guidelines. HDL determinations give 85% of the total group new information. Seventy percent

felt less anxious once they knew their HDL levels. Forty-two percent of the group (predominantly women and frequent exercisers) had HDL over 60 mg/dl. One-third of those persistently abnormal said they would go to their physician for follow-up. Favorable cholesterol/HDL ratios permitted realistic goal-setting for diet therapy. As diet reduction usually does not result in lowering over 20% of the total cholesterol, high HDLs permit a higher, safe cholesterol level. When low HDLs (below 28 mg/dl) existed, they were discovered from the outset and not obscured by a total cholesterol level that fell within the normal range.

Conclusion: The Danbury Hospital Preventive Cardiology Program recommends HDL levels be obtained initially at screenings for reduction of unfounded anxiety, for more realistic goal-setting, and for better cooperation among those tested in reporting for follow-up evaluations.

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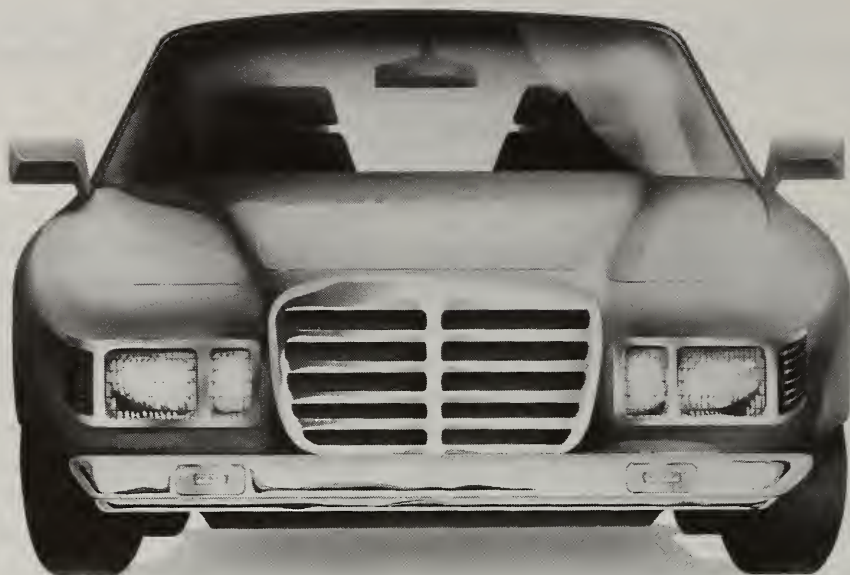
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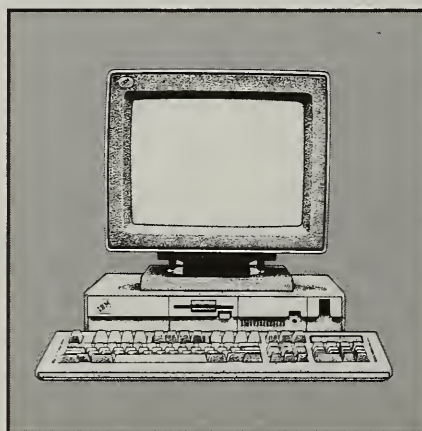
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Executive Summary, Report of the National Leadership Commission on Health Care

FORMED in 1986 by a group of concerned citizens to address the three major problems of cost, quality, and access to health care, the National Leadership Commission on Health Care proposes a major restructuring of the nation's health care system. The Commission's proposal provides universal access to a basic level of health services; it controls escalating costs through use of economic leverage in the purchase of care, economic incentives including cost sharing, and through practice guidelines to encourage appropriate care and eliminate unnecessary care, based on greatly expanded research on the quality and appropriateness of health care. The Commission believes that reducing unnecessary procedures will both contain costs and improve the quality of health care. Its malpractice reform recommendations will also help contain costs and improve quality.

The Commission brought together a distinguished group of leaders from many areas—health care, business, law, economics, politics, ethics, and labor. The Commission sought to develop a clear sense of the scope of the problems in health care, a vision to reach for, and workable solutions to bring us closer to that vision. It released an interim statement in June, 1987, outlining its view of the seriousness of the problems.

During its deliberations, the Commission agreed on a vision of a better health care system in the 21st century, one which promotes preventive care and healthy lifestyles, and establishes an innovative, efficient health care system that provides universal access to a basic level of appropriate, affordable care. The system would encourage personal responsibility for choosing good health and appropriate treatment, support a strong doctor-patient relationship, and promote a public-private partnership to control costs and improve the quality of care. It also proposes specific solutions to the malpractice crises.

The American health care system has done a remarkable job in many ways in providing health care to the American people. American medicine has long been a leader in the field, making significant contributions in the form of important new technologies to prevent and treat disease. Public and private insurance programs combine

to protect most Americans against devastating losses at vulnerable times of ill health and disability. Yet millions of Americans are disenfranchised, encountering barriers of entry to the health care system. Health care costs are escalating so rapidly that many payers have become alarmed at the upward spiral. And fundamental questions are now being asked about the quality, appropriateness and uncertainties of care being delivered.

Serious strains in the system are raising the frustrations of all who participate in it. Physicians are concerned about outside parties intruding on their clinical decisions and damaging the doctor-patient relationship. Hospitals find it increasingly difficult to cope with pressures for cost containment and with rapidly changing laws and regulations. Government and major private payers are trying with limited success to control rising costs. Patients are faced with higher costs, but they don't see care improving sufficiently to justify their increasing payments—and they continue to present the system with ever-increasing demands. Such strains in the health care system will be exacerbated by the rapid aging of the population, the AIDS epidemic, and the continuing technology explosion, which spawns more and more new treatments, that, though often beneficial, are also costly.

These problems grew out of the postwar period, which ushered in wonder drugs, sophisticated medical technology and the expansion of health insurance to cover the majority of the population. With the adoption of the Medicare and Medicaid programs in 1965, 85% of the population had some form of health insurance, leaving the consumers of health care shielded from, and thus much less sensitive to, cost increases than consumers in other sectors of the economy.

Cost

These developments have led to increases in health care expenditures that far outstrip general inflation rates. Factors fueling the cost increases include general inflation, accelerated inflation in medical care prices, the aging of the population, patient demand, increasing physician supply, the use of inappropriate care, the practice of defensive medicine, and advances in medical science leading to expensive new technologies—all compounded by the inherently inflationary ways in which most care is

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financed and delivered. The health care sector is one of the three largest sectors of the economy, so that inability to control costs in this area will have an important negative impact on the economy as a whole. Thus, serious concerns exist among government, American industry, and the American people about the cost issue. Furthermore, continued cost escalation in light of constrained resources could ultimately compromise everyone's access to care and further adversely affect its quality. To prevent this, it is imperative to bring costs under control.

Americans spent \$550 billion on health care in 1988, over 11% of GNP, far more than any other country. If these trends continue, costs will double by 1995 and triple by the turn of the century, hitting \$1.5 trillion in the year 2000. In that year, health care will consume 15% of GNP, and this country will spend \$5,551 on health care for every American man, woman, and child. The National Economic Commission estimates that if present trends continue, by the year 2005 the Medicare program alone will exceed in size either the Social Security or the defense budgets.

As a result, cost containment has become a rallying cry in both the private and public sectors. The federal government has enacted the prospective payment system (PPS) for hospitals, setting payment in advance according to a patient's diagnosis. Some state governments have instituted closely regulated global budgeting for hospitals and tight control on new construction. Private payers have turned to managed care mechanisms, such as health maintenance organizations (HMO's), as a way to hold down costs. Such efforts have successfully reduced inpatient hospital use, but they have also shifted costs to the outpatient setting, where costs have continued to rise rapidly.

Access

Increasing costs are accompanied by another disturbing development: growing numbers of people without health insurance, or with inadequate health insurance, and therefore without good access to health care. Financial strains on the Medicaid program mean that it now covers only 45% of those in need. Today about 37 million Americans lack insurance. A third of the uninsured are children. Perhaps an equal number have very inadequate coverage. Thus one out of every four Americans may be either uninsured or seriously underinsured. These people tend not to seek help until they are quite sick, which makes them more of a burden on the health care system than they would otherwise be.

Quality

Quality of care is the third area of major concern. We have insufficient information on the quality and outcomes of medical services and insufficient means of monitoring the quality of care and fostering its improvement. Recent studies have heightened this concern, citing large regional variations in the use of some medical services

that do not seem to be based on differences in medical need. Over the past two years, there has been a steady drumbeat of stories detailing the percentage of unnecessary and equivocal care in the use of one procedure after another. It has become clear to many experts that this is no longer a problem isolated to a few specialties but rather is generic to the health care of the nation. The sad fact is that our quality control systems are at best rudimentary. Hospitals, for example, have traditionally focused only on how care is delivered; they have just begun to measure the impact of that care on patient outcomes. Patients also have few tools to help them assess the quality and appropriateness of their treatment.

These critical problems in cost, quality, and access to health care in America present a clear and compelling case for change. They are interrelated problems that cry out for interrelated solutions. Piecemeal approaches have not worked in the past and will not in the future. Each problem can be solved effectively only in relation to the other two. Until we can better define quality and appropriate care, we cannot really know what is worth providing access to and what is worth paying for.

THE COMMISSION'S PROPOSAL

In response to these serious problems, the Commission proposes a new public/private partnership to optimize health outcomes and the use of economic resources. This strategy is designed to control costs, define and assure universal access to a basic level of health services and improve the quality and appropriateness of care.

Under our proposal, all Americans would be required to have health insurance for a package of basic services. There are several ways in which such coverage could be secured, including employment-based coverage, personal payments, or participation in our Universal Access (UNAC) program.

Our model calls for a shared responsibility to finance care for the currently uninsured. It retains a significant role for the states and private insurance companies. It is structured to strengthen market forces and foster competition and innovation in the quality and efficient management of health care services. The plan calls for a strong education campaign to encourage patients to adopt healthy lifestyles and to inform patients and providers about guidelines for appropriate care to help them make better decisions about treatment.

The Commission's strategy has the following additional elements:

- *Expand the existing insurance system* by encouraging all employers to provide health insurance for their employees.
- *Establish a nationally determined level of basic services* of health care available to all, allowing for state variations above that level.
- *Greatly increase research on the appropriateness, effectiveness, and quality of care* and publicize the results widely to help patients, providers, and payers assess treatment.

- *Control costs by reducing the amount of inappropriate care* as a result of the expanded research and national guidelines.
- *Encourage the marketplace to work more efficiently* by using new, solid information about appropriateness, quality, and cost, and by developing more cost-effective delivery systems.
- *Develop a strong public-private partnership to improve quality and control costs* by coordinating the expanded research on appropriateness and quality and disseminating the results through health professional and other appropriate organizations.
- *Develop and continually update national guidelines* to enable practitioners, patients, and payers to make more informed decisions.
- *Expand the existing state agencies* to operate the UNAC program and negotiate fair payment to providers who serve that population.
- *Promote nationwide the current, promising, state reforms in malpractice* and consider new federal initiatives if necessary.

A realistic strategy must not only deal with all three areas of cost, access, and quality; it must also engage all the parties which provide, pay for and use health care. This means that any effective system-wide solution must be a public-private partnership. The responsibility does not lie with the government alone, which pays for 40 percent of the country's health care bill, but also with private individual's and other private payers, who account for the other 60%.

While our systemic approach to reform is important, individual parts of the solution can be modified without endangering the integrity of the overall solution. For example, the source of the funding for improving access and expanded research could come from general revenues rather than a specific premium and fees. For illustrative purposes, our proposal sketches out the dimensions of one particular approach to funding. We recognize there are other possible approaches which could accomplish the same objectives.

Fundamental Principles

The Commission's proposal is based on seven fundamental principles which the Commission developed during its deliberations.

I. Principle of Universal Access:

There should be no financial barrier separating Americans in need of health care from access to available care.

II. Principle of Fair Compensation:

Every provider of health services in America should be adequately compensated for services rendered to patients.

III. Principle of Clinical and Economic Freedom:

To the maximum extent possible, without unduly compromising other important principles, health pol-

icy ought to restore clinical freedom in rendering health services and economic freedom in financing these services, within the context of adequate countervailing market power from those who ultimately pay for health care in America.

IV. Principle of Shared Responsibility:

Financial responsibility for health care for those too poor to afford it should be shared by government, individuals and employers.

V. Principle of Individual Responsibility:

To help achieve the goal of universal access to health care, the individual has a duty to have adequate health insurance coverage for him- or herself and dependent children.

VI. Principle of Basic Benefits Guarantee:

The design of a basic package of health-service benefits to which all Americans should have reliable access is ultimately a federal responsibility.

VII. Principle of a Strong Doctor-Patient Relationship:

Any health care system should foster the goal of protecting the integrity of the doctor-patient relationship.

The Commission's proposal builds upon the American tradition of providing private health insurance through the workplace. It is designed to encourage continued extensive reliance on that approach, without mandating that employers provide such coverage. The system thus preserves the pluralistic approach to health-care financing apparently preferred by Americans.

The National Leadership Commission does not consider it appropriate for it to establish the national basic benefits package for all Americans. The initial package would be set by enabling legislation. But the Commission strongly recommends that mental health benefits and preventive services, especially prenatal care, be included in this package.

Access to Care for All Americans

The Commission's proposal, known as the Universal Access or UNAC program, would extend health coverage to the 37 million Americans who now lack health insurance. All Americans would be covered at least for the national basic package of services. There are several ways they could obtain this coverage. Most Americans would probably continue to obtain privately-financed coverage as an employment benefit. Any American could also choose to purchase basic coverage or could supplement employer-provided coverage with personal funds. Older Americans would continue to receive Medicare coverage. Everyone else would receive coverage through the UNAC fund. The Commission proposes that all employers, and all individuals with incomes above 150% of the poverty level, pay a premium or a fee to finance health insurance for the uninsured. The Commission's plan uses strong incentives to encourage employers to offer coverage and to improve coverage under some

existing plans. It also has provisions for all individuals who can afford to do so to pay for part of their care.

The Commission has presented a plan in its report which details how this proposal could work in practice. The Commission believes the most reasonable estimate is that about 67.9 million people will become covered under the UNAC program. If all employers chose to provide insurance rather than pay the X_1 fee, the number in the program could be as small as 42.9 million. Estimates of the costs of various provisions of the proposal and how they would be financed are given in the full report.

Table 1
A Snap-Shot of Estimated Fees and Premiums^a (in 1988 figures; estimates include administrative costs)

		Basic-option ^b	Low-option ^a
Pay only in absence of health insurance	X_1 fee (employer)	9.68%	8.75%
	X_2 fee (employee)	2.04%	1.85%
Everyone pays (includes health services research)	Y premium (employer)	0.68%	0.58%
	Y premium (employee)	0.66%	0.56%

^aThe X_1 fee is a percentage of wages and salaries up to \$45,000. The X_2 fee and the Y premium are a percentage of adjusted gross income up to \$45,000.

^bThese different benefits plans are described in Technical Appendix I and Appendix B.

The Commission's UNAC safety net system would be administered at the state level by a cooperative effort involving all stakeholders in the health care system. The federal government would provide guidelines for the program designed to treat all Americans equally, regardless of location, but the program would not be centrally directed as is, for example, the Medicare program. There would be ample room for regional variations within broad federal guidelines.

In addition to a national package of basic health care benefits to which every American has access, the Commission's proposal allows the states to determine any additional benefits for their residents. The UNAC program would be administered by state agencies which would have the power to negotiate with providers and practitioners to establish the package and payment policies for UNAC beneficiaries. The Commission recommends the utilization of existing state agencies, where possible, rather than creation of a new level of bureaucracy. The Commission recommends that states broaden their agencies to include representatives of the major private stakeholders in health care—payers, practitioners, and consumers—perhaps appointed by state governors.

The Commission recognizes that it will not be easy to generate the cooperation needed to realize its goals, primarily because attitudes will have to change. But the Commission is unanimously convinced that cooperation is both desirable and possible. It is clear to the Commission from its discussions with dozens of physicians and

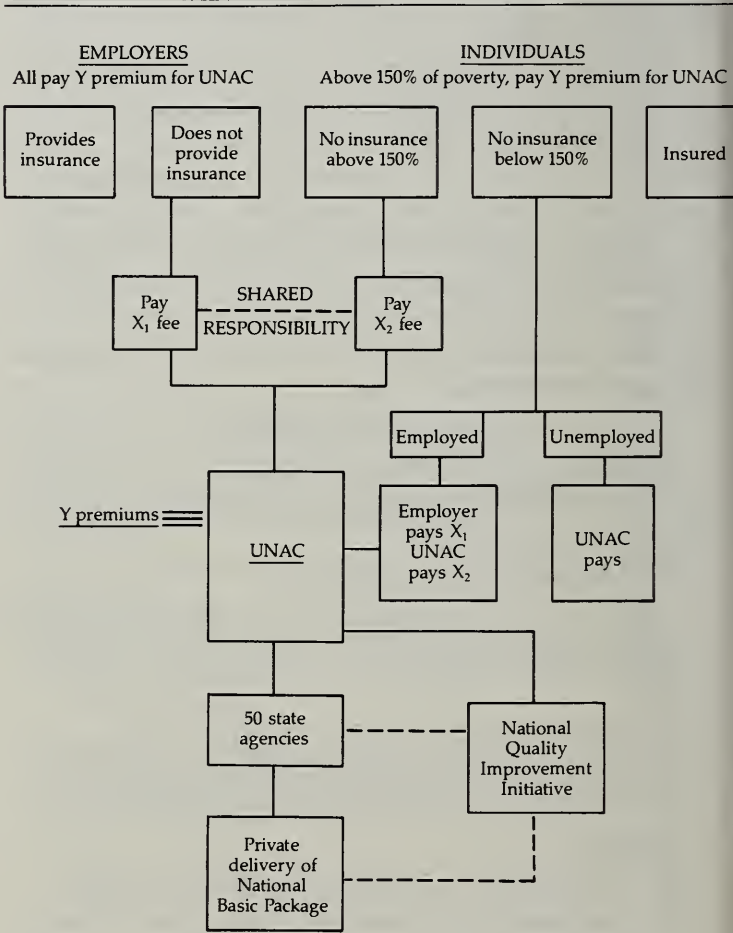
the testimony of leaders of the professions that they are eager to play a role in this process. The Commission regards their role as essential to the success of any proposed change in health care policy.

Cost Control and Quality Improvement

The Commission's approach to cost control goes beyond the provisions summarized above. It is also inextricably linked to its proposal for improving the quality and appropriateness of health care. The Commission plan seeks to remove cross-subsidies and make explicit the cost of care for all. Some or all of the cost of providing universal access would be made up in savings resulting from more appropriate care and improved quality control. The Commission's strategy is designed to improve both the value of care and the efficiency of the systems that provide care. A marketplace approach by definition, the Commission's proposal would greatly increase information available to providers and patients on the quality and appropriateness of health care. Such information, if widely disseminated, would allow the competitive advances of the past few years to play out.

The Commission has concluded that an important level of inappropriate over- and underuse of care has been documented for some time now. The reasons for inappropriate care include the following: an incomplete and continually evolving science base for that care, often creating uncertainty about appropriateness and effec-

Figure 1: Funding Mechanism for UNAC Program



tiveness in clinical decision making; perverse financial incentives; seeking to meet unrealistically high patient expectations; and the malpractice crisis. In addition, systems to assure that care is provided in the best fashion are too often inadequate.

Health professionals and patients need several types of knowledge. They need to know which tests and procedures are appropriate for an individual situation. When guidelines exist for particular conditions or treatments, they need to examine the scientific basis of those guidelines to determine its adequacy. They also need more information about which medical practices are truly effective and which are not. And they need better ways to measure what happens when care is provided and how it can be more effective. This can only occur within a general understanding that each patient presents a unique set of problems.

Improving information on quality and appropriateness will have far-reaching effects. In addition to reducing the level of uncertainty, which in turn reduces unnecessary and inappropriate care, improvements in quality and appropriateness information should also help stem the tide of increasing health care costs, increase efficiency, improve the doctor-patient relationship, and reduce defensive medicine and malpractice suits. Fortunately, there is solid evidence that health care providers will use relevant, well-presented information to improve the quality and appropriateness of their care. The Commission has found that governmental agencies and private organizations with clinical expertise are actively pursuing:

1. Objective analysis of the proper use of existing and emerging approaches to diagnosis and treatment, often known as appropriateness research and technology assessment;
2. Clinical trials on the effectiveness of medical practices;
3. Research designed to understand and, where appropriate, reduce practice variation, often known as outcomes research and practice pattern monitoring;
4. Synthesis of current research and clinical experience into practical clinical practice guidelines; and
5. Development and use of clinical and organizational measures to stimulate improvement in the quality and appropriateness of care.

National Quality Improvement Initiative. The Commission has found, however, that this work is woefully underfunded. The Commission has also found lacking a process where participants can develop a nationally coordinated strategy. The Commission proposes a National Quality Improvement Initiative that would fund such work and would involve periodic collective priority setting, coordination, and progress evaluation, while maintaining decentralized activities.

The Commission's plan would raise additional funds for this important research with a supplemental fee applied to the Y premium (see chart) for both employers and

individuals. We estimate that with a rate applied to both the employer and the employee Y revenue bases of about one-tenth of one percent (0.11%), the research fund would reach \$500 million per year.

At the Commission's request, Lewin/ICF prepared a very rough estimate of potential savings that could be generated by reducing inappropriate care. Based on HCFA estimates that as much as two percentage points of the annual hospital intensity index would be influenced by practice pattern changes, the Commission's estimate suggests a potential savings of two percentage points of the currently projected growth rate of health expenditure. This means that over a four-year period, about \$5.9 billion annually for Medicare Parts A and B combined could be influenced by changes in practice pattern. For national health expenditures, the figure is \$84 billion for fiscal year 1990-1993, or an average of \$22 billion annually that could be influenced by practice pattern changes. Using a second method of approximating the potential effects of changing practice patterns on health care costs, the Commission developed a very conservative "bottom up" estimate of potential savings from reducing inappropriate services; assuming a 4% growth rate in health expenditures annually, this estimate could approach \$1.5 billion a year by FY 1993.

Malpractice Reform

The Commission believes that the current system of malpractice litigation against providers of health care—hospitals, physicians, and nurses—impedes the delivery of economical, high quality care to American citizens. The Commission recognizes that patients should be fully compensated for injuries resulting from negligent care, and it supports strengthening procedures to identify and correct below-standard practices, but the present system of medical malpractice litigation does not achieve either goal and has other adverse consequences as well.

Malpractice litigation has driven up the cost of medical care overall and, in some specialties, at a dramatic rate. Providers who can obtain malpractice insurance are forced to pass on its rising cost to patients (or third-party payers) through increased fees. The fear of malpractice suits encourages defensive medicine, in which providers perform additional procedures, especially diagnostic ones, principally to protect themselves against law suits. Such procedures increase both the cost of care and sometimes health risks to patients. The current system of malpractice litigation also corrodes the patient-physician relationship.

We are, therefore, convinced that the malpractice system must be reformed, and we are encouraged by the breadth of interest in reform both within the medical profession and outside it. Some promising proposals have been adopted experimentally on a state or local basis, and we strongly support continued exploration of potential solutions and the adoption of the most promising reforms at the national level. Such proposals include

instituting strict criteria for expert witnesses in malpractice suits, strengthening standards of negligence, limiting punitive damages and contingency fees, and encouraging mediation and arbitration as alternatives to lawsuits for resolving disputes.

CONCLUSION

The Commission calls for a solution in three parts to a system undermined by three very serious problems. The problems are unnecessary, because we know how to solve them. They are larger than they ever needed to be because for years we understood them too little, we spent time blaming one party or another, and we did not have the scientific knowledge in some areas to respond to them. In recent years, we have found the will, we have learned that no single party is to blame, and we have developed the scientific ability to improve, to begin to

close the gap between art and science that has characterized medicine for many years. There will always be some art and some uncertainty, because our science continuously stretches into new areas and because every patient presents a unique set of problems. But today we have some promising methods for reducing uncertainty. It is incumbent on us to use them and to improve them continually to advance the quality and control the cost of care.

Above all, we are hopeful. Much has happened in just the two-and-a-half short years of the life of this Commission that indicates to us that all parties involved in analyzing, delivering, paying for, and benefiting from health care in this country are anxious to become involved in a solution that works. We hope that our strategies will suggest a way.

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The Conviction to Care

The McKinney Scholarship Fund

DEBORAH S. CHANG, J.D.

In response to the AIDS crisis and the critical need for competent and trained health care providers for the growing number of persons with AIDS, the McKinney Scholarship Fund has been recently established with the Stewart B. McKinney Foundation, and will be announced in December. As the first fund of its kind in the country, the McKinney Scholarship Fund will provide funding and financial assistance to qualified individuals who have demonstrated the ability and desire to go to school to work in the medical field with persons with AIDS, but who cannot afford to do so. At the present time, it is sponsored and endorsed by the Connecticut State Medical Society, the Hartford County Medical Association, the Connecticut Nurses' Association, the Hartford County Bar Association, and the Insurance Association of Connecticut.

IT is estimated that five to ten million people in the world are infected with the human immunodeficiency virus (HIV).¹ In Connecticut, an estimated 12,000 to 36,000 residents, or possibly *one out of every 100 residents*, are carrying and may be spreading HIV infection at the present time.² As of September of this year, 109,000 confirmed cases of the acquired immunodeficiency syndrome (AIDS) have been diagnosed in the United States.³ One thousand three hundred twenty of those cases were diagnosed in Connecticut.⁴ One out of every 58 mothers who gave birth in New Haven last year tested positive for HIV infection.⁵ By the end of this year it is estimated that between 90 to 160 infants will have been born to mothers with HIV infection in Connecticut alone.⁶

As staggering as these statistics may seem, they only tell part of the story. Statistics, even as shocking as these, are "human beings with the tears removed."⁷ It is impossible for these numbers to reflect the profound suffering that AIDS causes; nor can mere statistics indicate the dramatic effect of the epidemic on the medical profession and the health care workers who must deal with the harsh reality of the disease on a daily basis. These statis-

tics are worthless without an appreciation of the devastating, relentless, and terminal course of AIDS in a single patient, and the extraordinary strength and courage that are required to take care of that patient's physical, mental, and emotional needs.

As an attorney in the law firm of Day, Berry & Howard, I have, over this year, had the privilege of representing a class of prisoners afflicted with AIDS at the state's maximum security prison in an action which was filed against the Connecticut Department of Correction challenging the care and treatment of these prisoners.⁸ Through this case, I met the first person I ever knew with AIDS in March of 1988. Since that time and until an agreement was reached with the state this summer, I went to the "AIDS Ward" at the Connecticut Correctional Institution at Somers on at least a weekly basis, and witnessed over a dozen men under the age of 35 deteriorate and die from AIDS-related illnesses.

It is necessary to witness only one person die from an AIDS-related opportunistic infection in order to realize both the severity and the complexity of the disease. The ravaging effects of the wasting syndrome, the shortness of breath and high fevers associated with *Pneumocystis carinii* pneumonia, and the neurological deficits attendant to toxoplasmosis and AIDS dementia create indelible images that do not fade with time. It is not unusual for a patient in the end stages of AIDS to have numerous infections and lymphomas, each requiring extensive medication, invasive therapies, and consultation with a variety of specialists. Incontinent, weak, unable to eat any solid foods, and sometimes comatose, these patients require almost around-the-clock care and monitoring. As the numbers of these patients dramatically increase each year, and with no hope of a cure or vaccine in sight, the inevitable and disturbing question arises: Who will take care of all of these patients with this deadly and devastating disease?

One of the most frightening aspects of the AIDS crisis is the likely unavailability of sufficient numbers of trained and competent health care workers to provide the neces-

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sary services in the future. The number of experienced and trained physicians specialized to treat patients with HIV infection and AIDS is already limited.⁹ While the number of medical students who choose specialties involving high technology and lucrative salaries such as radiology, anesthesiology, and surgery steadily increases each year, there has been a recent decline in the number of medical students who select internal medicine, pediatrics, infectious diseases, and other specialties from which treating physicians of HIV infection and AIDS have necessarily been drawn.¹⁰ The situation is even more critical and noticeably apparent in the nursing profession.¹¹ The growing national shortage of nurses in hospitals raises considerable concern as to who will perform the vital function of providing physical comfort and care to patients with AIDS on a daily basis.¹²

The incredible physical and emotional demands placed on health care workers by the stressful nature of AIDS are undeniably factors which dissuade physicians, nurses and other professionals from specializing in the care of patients with AIDS. Caring for chronically and terminally ill patients is difficult in and of itself. The care of AIDS patients, however, is additionally laden with the psychological burdens caused by the lurking fear of transmission of the disease as well as the inherent prejudices and biases toward the groups that are at high risk for contraction of the disease.

The devastating and tragic nature of AIDS, however, has in some ways, provided a unique opportunity for us all to examine the strength of our convictions and to test our own potential for caring, courage, and selflessness. Throughout history physicians and health care professionals have had to confront the casualties and victims of plagues, epidemics, and wars at the sacrifice of their own personal safety. It is essential for the medical community now to concentrate on creative and drastic measures to ensure the future recruitment, training, and retention of qualified and dedicated health care providers to treat patients with AIDS.¹³

It is in this spirit that the McKinney Scholarship Fund has been established with the Stewart B. McKinney Foundation. For the first time in this country a scholarship will be provided to qualified individuals who wish to work in the medical field with persons with AIDS. Numerous professional organizations comprising the interests of medical and legal professionals will be consolidating their efforts to ensure the success of this crucial scholarship fund. A committee consisting of representatives of the medical, legal, business, and educational communities is presently being formed to coordinate the fund-raising and administrative aspects of this venture. The scholarship will provide funds for both tuition and living expenses to selected individuals for medical or nursing school in an effort to provide competent and appropriately trained physicians and nurses to meet the needs presented by the AIDS crisis.

The endorsement of this fund by and the efforts of

organizations such as the Connecticut State Medical Society, the Hartford County Medical Association, the Connecticut Nurses' Association, the Hartford County Bar Association and the Insurance Association of Connecticut indicate these organizations' recognition of and commitment to this crisis. Through the consolidated efforts of these organizations, individuals who otherwise would never be able to go to medical or nursing school because of financial constraints will have the opportunity to do so. The first scholarship will be presented next year.

The creation of this scholarship fund resulted, oddly enough, from a lawsuit. In the course of the litigation of our class action on behalf of the prisoners with AIDS at Somers, I encountered Russell V. Schuetz, Jr. a correctional attendant trained as an emergency medical technician, and the first recipient of the McKinney Scholarship. Although Russ Schuetz had always wanted to go to school to become a registered nurse so that he could work with patients with AIDS, financial constraints and family responsibilities made it impossible for him to do so. The following excerpts from a letter which I sent to Mr. Gary Smith, the Executive Director of the Stewart B. McKinney Foundation, describe Russ Schuetz and the reason for the creation of the scholarship fund:

Dear Mr. Smith:

Pursuant to our telephone conversation several weeks ago, I am providing this letter to document the facts of which I am aware relating to Russell Schuetz, the medical correctional attendant who desires to go to nursing school so that he can work with persons with AIDS. As you know, I believe that it is important to bring this person to your attention because of his unique display of ability, dedication, and compassion to those who suffer from AIDS.

Russell Schuetz is presently employed as a correctional attendant at the Connecticut Correctional Institution at Somers, the state's maximum security prison. Since approximately 1984, he has worked intensively with the inmates with AIDS who are hospitalized there. His performance and character have so impressed all of us at this firm that I felt compelled to contact you to discuss his situation with you.

This firm represents a class of prisoners afflicted with AIDS who are incarcerated at Somers in an action filed against the Connecticut Department of Correction. Since March of 1988, we have conducted extensive discovery regarding the care and treatment of prisoners with AIDS at Somers, and have visited the prison at least once a week. Our pretrial investigation included intensive reviews of medical records, depositions and interviews with employees and physicians, interrogatory requests propounded to the state, and extensive interviews and videotaped depositions of the prisoners with AIDS. Needless to say, I have become very familiar with both the prison and the people who work there. During this time period, we consistently heard numerous favorable reports from the physicians and the inmates about Russ Schuetz. Over this last year, I have had the pleasure of getting to know him, and never cease to be amazed at his willingness to help those unfortunate persons who are afflicted with this disease.

Let me preface my remarks by saying that we started the discovery in this lawsuit with the intention of discovering and disclosing all of the inadequacies of the medical care being administered to our class members at Somers. We deposed

many of the staff members there, including Russ, with the purpose of testing their experience and knowledge on the subject of AIDS. A panel of national medical experts reviewed the depositions and medical records in elaborate detail. We certainly never expected to find a person like Russ, who is so obviously dedicated to extending comfort and compassion to inmates with AIDS, and whose knowledge about the disease is truly impressive. Litigation, however, sometimes has the unique tendency to expose unexpected truths and reveal both the good and the bad of people and places in an efficient and reliable manner.

Our discovery in this case revealed that the only "hospital" which provides inpatient care for male inmates in the Department of Correction is at Somers, on Hospital III. As a result, all of the male inmates who are afflicted with AIDS were sent to Somers. Unfortunately, the number of inmates with AIDS has grown over the years and will continue to increase until a cure is found. It is estimated that over 80% of the prisoners at Somers have a history of IV drug abuse.

Hospital III at Somers can house up to thirty or more inpatients, and the floor is often filled to capacity. Until very recently, an AIDS ward housed all of the inmates with full-blown AIDS on a permanent basis. The conditions of these patients ranged from those who were moderately healthy and asymptomatic to those who were severely ill and at the end stage of AIDS.

Russ is approximately thirty years old and graduated from Bethel High School in Bethel, Connecticut, in 1976. He is trained as an emergency medical technician and started working for the Department of Correction in February of 1982. As a correctional attendant, he works on Hospital III under the direct supervision of nurses and doctors on that floor, and performs various duties relating to direct patient care.

His experience and knowledge about the disease and the treatment for various opportunistic infections surpass many of the registered nurses there. He has been relied upon for identifying symptoms of infections and treatment alternatives by both the physicians and other staff members on that floor. In fact, he has been referred to several times by other staff members as the "expert" on AIDS on Hospital III. The rest of the staff seem to follow his lead and he assumes this role without hesitation or reluctance. Since there is no formal training or education of the correctional attendants on the subject of AIDS, Russ has acquired much of his knowledge on his own by reading and studying on his own time.

In the world of prisons and correctional management, staff members are extremely reluctant to befriend an inmate or even show them any sign of compassion which could be misconstrued for weakness. In addition, staff members exhibit great fear and reluctance when dealing with inmates with AIDS or HIV infection. Despite these facts, Russ has managed to go above and beyond the call for the inmates entrusted to his care.

One of these inmates, Manny, died last year. Manny was 30 years old, and had suffered from a variety of infections, including *Pneumocystis Carinii* pneumonia, wasting syndrome, thrush and seizure disorders. He was approximately 6'1" tall, and when healthy, weighed over 200 lbs. By the time that he died, he had wasted to 80 lbs. His appearance was so disturbing that many staff members could not bear to look at him or care for him. Manny required total patient care, as he was incontinent and could not even feed himself.

Russ assumed the care for Manny because many of the other members of the nursing staff who were working there were reluctant to do so. As his condition deteriorated, Manny

wanted to talk about dying, which also made people uncomfortable. Russ made himself available to Manny twenty-four hours a day, and would call in to check on him when he was not working. During the day, he would frequently bathe Manny, take care of his continual diarrhea, and feed him. Because Manny was afraid of dying alone in prison, Russ often stayed with him all night long. He volunteered to work every midnight shift possible so that he could be with Manny. When the other prisoners on the floor went outside for recreation, Russ covered Manny's frail body with a blanket and wheeled him out in a wheelchair so that he could get some fresh air. Because Manny could not wash his own clothes, Russ took his dirty laundry to his own home to wash them. Most importantly, Russ managed to step over the line drawn between prisoners and staff members, which in turn affected the attitudes of many other staff members at the prison.

The inmates with AIDS soon began to trust and rely upon Russ, often requesting him when they became ill. Time after time, inmates relayed to us circumstances in which they would "wait for Russ" so that they could be assured of getting attention and treatment. Because they believed that the other staff members ignored them, Russ became their primary source of assistance. He is one of the few staff members there who explains the disease and various treatments to the inmates.

His compassion, however, is not limited to those inmates who are incarcerated at the prison. In December, we were successful in securing the release of a young inmate in his last stages of AIDS. Jose was barely 24 years old when he died at home in February of this year. Of all of the inmates I have worked and will work with, Jose is the most unforgettable. He has a special place in my heart because he was so young and so unwilling to accept his own mortality. I have never met anyone who was more afraid of death than Jose. When he was deathly ill, he demanded that a radio be kept on at all times so that he would never have to be alone in silence. I often thought that he believed that death would overtake him in the quiet of the night.

Jose lived in one of the worst sections in New Haven. Although we arranged for Hospice nurses and volunteers to be with him, many were afraid to go to his neighborhood at night. When Russ found out that they were not going to Jose's house, he took it upon himself to drive from Somers to New Haven—over an hour trip each way—to bathe and care for him. These trips were all on unpaid time. In fact, the prison never knew that he was doing this.

I visited Jose twice at his house in New Haven with Russ. My last memories of Jose will always be of him lying on the bed with Russ holding his hand. Jose had wasted down to about 80 lbs. He was losing his hair and he could not breathe without great difficulty. He required the assistance of oxygen to breathe. Jose's family, although supportive, refused to talk about death. Russ was the only person Jose could talk to about dying. He made himself available to Jose twenty-four hours a day, giving him his home telephone number and telling him to call collect, at any time of the day.

Russ was with Jose the night before he died. Although Jose had been in a semicomatose state all day, he became conscious and very talkative at about 2:00 or 3:00 in the morning. Russ stayed the entire night and morning with him. At the wake and funeral service, I noticed that Jose's family treated Russ as if he were a member of their own family. The love and devotion that he displayed to that family both amazed and touched me.

The morale of the staff at Somers is not always very high. Unfortunately, the medical staff works long hours at minimal

pay. The addition of seriously ill patients on the floor places a tremendous burden on the staff. The energy level that Russ maintains, however, is actually contagious to the rest of the floor. He motivates and leads the rest of the staff to do the work that is needed, and often takes it upon himself to ensure the quality of care that is being administered. It is obvious that he is truly fulfilled by helping others in need of medical assistance.

I strongly believe that Russ has earned the right to go to nursing school, and that all efforts should be made to find a way for him to go. It is ironic that in today's society, where it is so difficult to find a registered nurse to work with patients with AIDS, a person who *wants* to work with them finds it difficult, if not impossible, to do so because of financial limitations. I hope that you and your organization can help us to find a way for Russ to achieve this goal.

I am very proud to have had the opportunity to get to know Russ. He and his wife have been an inspiration to all of us who work with AIDS issues and people afflicted with AIDS. I have found it somewhat unfair, however, that while this firm continuously receives tremendous publicity and accolades for taking on a case of this magnitude for prisoners with AIDS, people like Russ, who devote so much of themselves and their lives to these prisoners on a daily basis, receive no praise or gratitude for their extraordinary efforts.

Since this letter was written in April of this year, Russ has continued to make it possible for many patients to die with a sense of peace and acceptance of the inevitable. Through Russ I have come to realize the rewards of having the conviction to care, namely having the opportunity to witness the depth of human strength and determination and to understand the immeasurable value of life.

Perhaps one of the most important lessons that Russ has taught us is that we can all do something about this

disease. I believe that someday a cure for AIDS will be found, and historians will look back upon these days and examine what we did and how we reacted to this crisis and to the thousands of persons afflicted with the disease. The McKinney Scholarship Fund demonstrates that we have done something of crucial importance. We are at last helping to ensure that they will be cared for by competent and compassionate medical professionals in the future.

For more information, please contact
The McKinney Scholarship Fund
c/o The Stewart B. McKinney Foundation, Inc.
P.O. Box 338
Fairfield, Connecticut 06430

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12. Cotton D: The impact of AIDS on the medical care system, *JAMA* 1988;260:514-20.
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Drugs for Hypertension

THE MEDICAL LETTER

DRUGS available in the USA for treatment of chronic hypertension, their dosages and adverse effects, are listed in the table beginning on page 671. A thiazide-type diuretic or a beta-adrenergic blocker has traditionally been the first drug used for treatment of hypertension, but many clinicians now start with an angiotensin-converting enzyme (ACE) inhibitor or a calcium-entry blocker (1988 Joint National Committee, *Arch Intern Med*, 148:1023, 1988). If the first drug is ineffective or poorly tolerated, another type of drug can be substituted. If more than one drug is necessary and a diuretic was not used initially, most clinicians would add a diuretic.

DIURETICS — Many **thiazide-type diuretics** are used to treat hypertension; all have similar effects, except that metolazone (*Zaroxolyn*; *Diulo*; *Mykrox*) may be effective in patients with impaired renal function when thiazides are not. Thiazide-type diuretics can add to the effectiveness of other antihypertensive drugs and reverse the fluid retention that occurs with some. Many patients can be treated with very small doses of diuretics, equivalent to 12.5 mg to 25 mg of hydrochlorothiazide (*Esidrix*; and others) once daily.

The loop diuretics **furosemide** (*Lasix*; and others) and **bumetanide** (*Bumex*) have a shorter duration of action than thiazide-type diuretics, and Medical Letter consultants believe they are less effective for treatment of hypertension. They should be reserved for hypertensive patients with fluid retention refractory to thiazides or for patients with impaired renal function; since they have a different site of action, loop diuretics may be effective for such patients when thiazides are not.

Potassium-retaining diuretics are used mainly with other diuretics to prevent or correct hypokalemia. They can cause life-threatening hyperkalemia in patients with renal impairment; serum potassium concentrations must be monitored, particularly in diabetics, the elderly, patients with renal failure and those taking other drugs that can decrease aldosterone secretion, such as ACE inhibitors. **Amiloride** (*Midamor*; and others) is a potas-

sium-retaining diuretic with a small antihypertensive effect that can add to that of the thiazides. The aldosterone antagonist **spironolactone** (*Aldactone*; and others) also has antihypertensive activity, but causes more troublesome adverse effects. **Triamterene** (*Dyrenium*), also a potassium-sparing diuretic, is not an effective antihypertensive agent when used alone.

DRUGS WITH PERIPHERAL SYMPATHOLYTIC ACTION — Beta-adrenergic blocking drugs are usually well tolerated for initial treatment of hypertension. Although generally less effective than thiazides in black or elderly patients and in smokers, beta-blockers sometimes produce a good response even in these patients. All currently available beta-blockers appear to be equally effective for treatment of hypertension. Beta-blockers can aggravate congestive heart failure, and should not be used in hypertensive patients with peripheral vascular disease, asthma or other obstructive pulmonary disease. In diabetic patients with a tendency toward hypoglycemic events, beta-blockers should be used with caution because they can mask the symptoms of hypoglycemia. When used alone as initial therapy, the incidence of adverse effects requiring withdrawal has generally been similar with either a beta-blocker or a thiazide.

Propranolol (*Inderal*; and others), **timolol** (*Blocadren*), **nadolol** (*Corgard*), **pindolol** (*Visken*), **penbutolol** (*Levitol*) and **carteolol** (*Cartrol*) are "nonselective" beta-blockers; **metoprolol** (*Lopressor*), **acebutolol** (*Sectral*), and **atenolol** (*Tenormin*) in low doses are "cardioselective," with a greater effect on cardiac (β_1) adrenoreceptors than on β_2 -adrenergic receptors of the bronchi and blood vessels. Selectivity is an advantage for diabetic patients because selective beta-blockers are less likely to delay recovery from hypoglycemia or to cause severe hypertension when circulating epinephrine increases during hypoglycemia (*Medical Letter*, 28:20, 1986). However, they become less selective as dosage is increased, and even low doses can cause bronchospasm in susceptible patients.

Pindolol, **acebutolol**, **penbutolol** and **carteolol** are beta-blockers with intrinsic sympathomimetic activity (*Medical Letter*, 25:13, 1983; 27:58, 1985); they can lower blood pressure with less decrease in cardiac output or

heart rate at rest, and may be preferred for patients who develop symptomatic bradycardia with other beta-blockers. Those with intrinsic sympathomimetic activity, unlike other beta-blockers, apparently do not increase serum triglyceride concentrations or decrease high-density lipoprotein cholesterol.

Labetalol (*Trandate; Normodyne*) combines nonselective beta-blockade and intrinsic sympathomimetic activity with vascular postsynaptic alpha-adrenergic receptor blockade (*Medical Letter*, 26:83, 1984). These two properties exist on separate molecules (stereoisomers) present in equimolar quantities. Labetalol is therefore actually a fixed-dose combination rather than a single drug. Labetalol decreases blood pressure more promptly than other beta-blockers and can be used intravenously to treat hypertensive emergencies, but in chronic use orthostatic hypotension and sexual dysfunction may be more frequent than with other beta-blockers.

Prazosin (*Minipress*) blocks vascular postsynaptic alpha-adrenergic receptors, resulting in arterial and venous dilatation. It causes less tachycardia than hydralazine, but more frequent postural hypotension. One to three hours after the first dose of prazosin, profound orthostatic hypotension with syncope can occur, particularly in patients who have low plasma volume (possibly due to diuretic therapy) or are taking other antihypertensive drugs. Hypotensive syncope can usually be avoided by giving a small initial dose of 1 mg at bedtime and cautioning the patient not to rise for at least three hours. This syndrome usually does not occur with subsequent doses but can recur when the dose is increased. Salt and water retention and tolerance to the drug can develop with long-term treatment.

Terazosin (*Hytrin - Medical Letter*, 29:112, 1987) is an alpha₁-adrenergic blocker with a longer half-life (12 hours) and duration of action (up to 24 hours) than prazosin. As with prazosin, the first dose of terazosin produces greater orthostatic hypotension than subsequent doses and should be taken at bedtime.

Reserpine (many manufacturers) is an effective antihypertensive agent; other rauwolfia alkaloids and mixtures have no advantage over reserpine. Current or past depression is a contraindication to the use of these drugs, but severe drug-induced depression can occur insidiously in patients without such a history. If reserpine is used, it should generally be in a dose of 0.1 mg daily, given concurrently with a thiazide. Doses as low as 0.05 mg daily can be effective.

Guanethidine (*Ismelin*) usually decreases cardiac output and lowers systolic pressure more than diastolic. Postural and exertional hypotension caused by the drug are aggravated by anything that promotes vasodilation, including a hot environment, exercise or alcohol. Ejaculatory problems and diarrhea are common. Because of these adverse effects, some Medical Letter consultants advise against using guanethidine. **Guanadrel** (*Hylorel*) is similar to guanethidine, with a much shorter duration of action.

ANGIOTENSIN-CONVERTING ENZYME (ACE) INHIBITORS — Captopril, enalapril and lisinopril

appear to be similar in effectiveness for treatment of hypertension. Patients with high levels of plasma renin activity may have excessive hypotensive responses to these drugs; such patients include those who are volume-depleted or on diuretics, and those with renovascular hypertension or congestive heart failure, particularly when it is associated with hyponatremia. Diuretics may best be discontinued before starting these drugs and restarted later if necessary. For hypertension in black patients, an ACE inhibitor alone may be less effective than a diuretic. Cough unresponsive to medication occurs in many patients treated with ACE inhibitors (RC Goldsizer et al, *Am J Med*, 85:887, Dec 1988). Bronchospasm has also been reported (CE Bucknall et al, *Br Med J*, 296:86, 1988). Hyperkalemia can occur, particularly in patients taking potassium supplements or potassium-sparing diuretics. ACE inhibitors should not be used during pregnancy.

Captopril (*Capoten*) was first marketed only for severe hypertension because of concern about hematological and renal toxicity, but now is also approved for use in low doses to treat mild to moderate hypertension in patients with normal renal function (*Medical Letter*, 27:103, 1985). Used alone, captopril is probably no more effective than a thiazide diuretic, but may be better tolerated (SH Croog et al, *N Engl J Med*, 314:1657, 1986). **Enalapril** (*Vasotec*) has a slower onset of action than captopril but a longer duration, permitting once-daily therapy for many patients (*Medical Letter*, 28:53, 1986). Enalapril has generally been well tolerated; whether it has fewer adverse effects than captopril is still unclear. **Lisinopril** (*Prinivil; Zestril*), the newest ACE inhibitor marketed in the USA (*Medical Letter*, 30:41, 1988), is a derivative of enalapril with similar therapeutic and adverse effects but slower absorption and onset of action.

CALCIUM-ENTRY BLOCKERS — **Verapamil** (*Calan; Isoptin*; and others), **diltiazem** (*Cardizem SR*) and **nicardipine** (*Cardene*) have been approved in the USA for use in hypertension; **nifedipine** (*Procardia; Adalat*) is still under investigation. All of these drugs cause vasodilatation, which decreases peripheral resistance. The cardiac response to the decrease in vascular resistance is variable; with nifedipine or nicardipine, an initial reflex increase in heart rate usually occurs, but verapamil and diltiazem cause little or no change in heart rate. Diltiazem and verapamil can adversely affect atrioventricular (AV) conduction and should not be used at the same time as a beta-blocker. All of the calcium-entry blockers should be used with caution in patients with heart failure. When combined with diuretics, calcium blockers may have less of an additive antihypertensive effect than other antihypertensive drugs (JP Nicholson et al, *Arch Intern Med*, 149:125, Jan 1989).

DRUGS WITH CENTRAL SYMPATHOLYTIC ACTION — Drugs in this category do not inhibit reflex responses as completely as sympatholytic drugs that act peripherally.

Methyldopa (*Aldomet*; and others) frequently causes dry mouth, sedation and lethargy that may be transient but can be quite disabling. Postural hypotension is less

SOME ORAL ANTIHYPERTENSIVE DRUGS

Drug	Daily Adult Dosage	Frequent or Severe Adverse Effects*
ANGIOTENSIN-CONVERTING ENZYME (ACE) INHIBITORS		
Captopril (<i>Capoten</i>)	Initial: 25-50 mg in 2 doses Maintenance: 50-300 mg in 2 doses	Hypotension, particularly with a diuretic or volume depletion; loss of taste with anorexia; skin rash; cough; bronchospasm; acute renal failure with bilateral renal artery stenosis or stenosis of the artery to a solitary kidney; cholestatic jaundice; angioedema; hyperkalemia if also on potassium supplements or potassium-retaining diuretics; blood dyscrasias and renal damage are rare except in patients with renal dysfunction, and particularly in patients with collagen-vascular disease; may increase fetal mortality and should not be used during pregnancy
Enalapril (<i>Vasotec</i>)	Initial: 2.5-5 mg in one dose Maintenance: 5-40 mg in 1 or 2 doses	Similar to captopril; manufacturer of enalapril claims lower incidence of some effects, but comparative data are limited
Lisinopril (<i>Prinivil</i> , <i>Zestril</i>)	5-40 mg in 1 dose	Similar to enalapril
CALCIUM-ENTRY BLOCKERS		
Diltiazem (<i>Cardizem SR</i>)	60-120 mg twice daily	Similar to verapamil
Nicardipine (<i>Cardene</i>)	20-40 mg three times daily	Similar to verapamil, but more likely to cause edema, and less likely to cause constipation or AV block; may cause tachycardia
Verapamil (<i>Calan</i> ; <i>Isoptin</i> ; others)	120-480 mg in 2 or 3 doses (<i>Isoptin SR</i> and <i>Calan SR</i> can be given 240 mg once or twice daily)	Heart failure; hypotension; AV block; constipation; dizziness; edema; headache; bradycardia; gynecomastia
DIURETICS		
THIAZIDE-TYPE (Usually once daily)		Hyperuricemia; hypokalemia; hypomagnesemia; hyperglycemia; hyponatremia; hypercalcemia; pancreatitis; rashes and other allergic reactions; increased serum low density lipoprotein cholesterol and triglyceride concentrations; depression; impotence
Bendroflumethiazide (<i>Naturetin</i>)	2.5-5 mg	
Benzthiazide (<i>Exna</i> ; others)	12.5-50 mg	
Chlorothiazide (<i>Diuril</i> ; others)	125-500 mg	
Cyclothiazide (<i>Anhydron</i>)	1-2 mg	
Hydrochlorothiazide (<i>Esidrix</i> ; others)	12.5-50 mg	
Hydroflumethiazide (<i>Saluron</i> ; others)	12.5-50 mg	
Methyclothiazide (<i>Enduron</i> ; others)	2.5-5 mg	
Polythiazide (<i>Renese</i>)	2-4 mg	
Trichlormethiazide (<i>Naqua</i> ; others)	1-4 mg	
Chlorthalidone (<i>Hygroton</i> ; others)	12.5-50 mg	
Indapamide (<i>Lozol</i>)	2.5 mg	
Metolazone (<i>Zaroxolyn</i> ; <i>Diulo</i>)	1.25-10 mg	
Metolazone (<i>Mykrox</i>)	0.5-1 mg	
Quinethazone (<i>Hydromox</i>)	25-200 mg	
LOOP DIURETICS		Dehydration; circulatory collapse; thromboembolism; hypokalemia; hypomagnesemia; hypocalcemia; hyperglycemia; metabolic alkalosis; hyperuricemia; blood dyscrasias; rashes; lipid changes as with thiazide-type diuretics
Bumetanide (<i>Bumex</i>)	0.5-10 mg in 2 to 3 doses	
Furosemide (<i>Lasix</i> ; others)	40-320 mg in 2 to 3 doses	
POTASSIUM-RETAINING		
Amiloride (<i>Midamor</i> ; others)	5-10 mg in 1 dose	Hyperkalemia; GI disturbances; rash; headache
Spironolactone (<i>Aldactone</i> ; others)	25-100 mg in 1 or 2 doses	Hyperkalemia; hyponatremia; gynecomastia; agranulocytosis; menstrual abnormalities; GI disturbances; rash; tumorigenic in rats
Triamterene (<i>Dyrenium</i>)	50-200 mg	Hyperkalemia; GI disturbances; increased blood urea nitrogen; metabolic acidosis; nephrolithiasis
SOME COMBINATIONS		
<i>Aldactazide</i> (hydrochlorothiazide 25 mg and spironolactone 25 mg)	1-2 tablets daily	Similar to individual components
<i>Dyazide</i> (hydrochlorothiazide 25 mg and triamterene 50 mg)	1-2 tablets daily	
<i>Maxzide</i> (hydrochlorothiazide 25 or 50 mg and triamterene 37.5 or 75 mg)	1 tablet daily	
<i>Moduretic</i> (hydrochlorothiazide 50 mg and amiloride 5 mg)	1/2-1 tablet daily	

Drug	Daily Adult Dosage	Frequent or Severe Adverse Effects*
DRUGS WITH PERIPHERAL SYMPATHOLYTIC ACTION		
BETA-ADRENERGIC BLOCKING DRUGS		
Acebutolol (<i>Sectral</i>)	400-1200 mg in 1 or 2 doses	Similar to propranolol, but relatively cardioselective, with less lipid changes and resting bradycardia and more antinuclear antibodies; occasional drug-induced lupus
Atenolol (<i>Tenormin</i>)	50-100 mg in 1 dose	Similar to propranolol; relatively cardioselective at ≤ 100 mg/d
Carteolol (<i>Cartrol</i>)	2.5-10 mg in 1 dose	Similar to propranolol, but less resting bradycardia and lipid changes; asthenia and muscle cramps
Labetalol (<i>Trandate</i> ; <i>Normodyne</i>)	200-1200 mg in 2 doses	Similar to propranolol but more orthostatic hypotension; fever
Metoprolol (<i>Lopressor</i>)	Initial: 50 mg in 1 or 2 doses Maintenance: 100-200 mg in 1 or 2 doses	Similar to propranolol; at doses < 200 mg is relatively cardioselective
Nadolol (<i>Corgard</i>)	Initial: 20 mg in 1 dose Maintenance: 80-160 mg in 1 dose	Similar to propranolol
Penbutolol (<i>Levitol</i>)	Initial: 20 mg in 1 dose Maintenance: 10-40 mg in 1 dose	Similar to propranolol, but less resting bradycardia and lipid changes
Pindolol (<i>Visken</i>)	10-40 mg in 2 doses	Similar to propranolol, but less resting bradycardia and lipid changes
Propranolol (<i>Inderal</i> ; others)	Initial: 40-160 mg in 2 doses Maintenance: 80-320 mg in 2 doses (<i>Inderal LA</i> can be given in one daily dose)	Fatigue; bradycardia; decreased exercise tolerance; congestive heart failure; aggravates peripheral vascular disease; depression; GI disturbances; increased airway resistance; masks symptoms of hypoglycemia; Raynaud's phenomenon; vivid dreams or hallucinations; organic brain syndrome; rare blood dyscrasias and other allergic disorders; increased serum triglycerides, decreased HDL cholesterol; generalized pustular psoriasis; transient hearing loss; sudden withdrawal can lead to exacerbation of angina and myocardial infarction
Timolol (<i>Blocadren</i>)	10-20 mg in 2 doses	Similar to propranolol
PERIPHERAL ADRENERGIC NEURON ANTAGONISTS		
Guanadrel (<i>Hylorel</i>)	10-50 mg in 2 doses	Similar to guanethidine, but less diarrhea; aggravation of asthma has not been reported
Guanethidine (<i>Ismelin</i>)	10-300 mg in 1 dose	Orthostatic hypotension; exercise hypotension; diarrhea; may aggravate bronchial asthma; bradycardia; sodium and water retention; retrograde ejaculation
Reserpine (<i>Serpasil</i> ; others)	0.05-0.25 mg in 1 dose	Psychic depression; nightmares; nasal stuffiness; drowsiness; GI disturbances; bradycardia
ALPHA-ADRENERGIC BLOCKERS		
Prazosin (<i>Minipress</i>)	First day: 1 mg at bedtime Maintenance: 1-20 mg in 2 doses	Syncope with first dose; dizziness and vertigo; palpitations; fluid retention; headache; drowsiness; weakness; anticholinergic effects; priapism; urinary incontinence
Terazosin (<i>Hytrin</i>)	First day: 1 mg at bedtime Maintenance: 1-20 mg in 1 dose	Syncope with first dose; dizziness and vertigo; palpitations; fluid retention; headache; drowsiness; weakness; anticholinergic effects; priapism; urinary incontinence
DRUGS WITH CENTRAL SYMPATHOLYTIC ACTION		
Clonidine (<i>Catapres</i> ; others) (<i>Catapres TTS</i> ; transdermal)	0.1-0.6 mg in 2 doses one patch weekly (0.1 to 0.3 mg/day)	Severe insomnia and rebound hypertension; headache; cardiac arrhythmias after sudden withdrawal; CNS reactions similar to methyl dopa, but more sedation and dry mouth; bradycardia; contact dermatitis from patches
Guanabenz (<i>Wytensin</i>)	8-32 mg in 2 doses	Similar to clonidine
Guanfacine (<i>Tenex</i>)	1-3 mg in 1 or 2 doses	Similar to clonidine, but milder
Methyl dopa (<i>Aldomet</i> ; others)	500 mg-2 grams in 2 doses	Sedation and other CNS symptoms; fever; orthostatic hypotension; bradycardia; GI disorders, including colitis; hepatitis; cirrhosis; hepatic necrosis; Coombs' positive hemolytic anemia; lupus-like syndrome; immune thrombocytopenia; red cell aplasia
DIRECT VASODILATORS		
Hydralazine (<i>Apresoline</i> ; others)	40-300 mg in 4 doses	GI disturbances; tachycardia; aggravation of angina; headache and dizziness; fluid retention; nasal congestion; rashes and other allergic reactions; lupus-like syndrome; hepatitis; glomerulonephritis
Minoxidil (<i>Loniten</i> ; others)	First day: 5 mg Maintenance: up to 100 mg/day; usually 10-40 mg is adequate	Tachycardia; aggravation of angina; marked fluid retention; possible pericardial effusion; hair growth on face and body; coarsening of facial features; thrombocytopenia; leukopenia

* Most antihypertensive drugs can probably cause sexual dysfunction (Medical Letter, 29:65, 1987).

frequent than with guanethidine, but methyldopa has other severe adverse effects that limit its usefulness.

Clonidine (*Catapres*; and others) has antihypertensive effects similar to those of methyldopa. A severe rebound in blood pressure may occur if the drug is discontinued abruptly, especially after high-dose, long-term treatment or with a concomitant beta-blocker. Clonidine is available in transdermal patches (*Catapres-TTS*) that can be applied once weekly (*Medical Letter*, 27:95, 1985); rebound hypertension has been reported when the patches were discontinued (S Metz et al, *Am J Med* 82:17, 1987).

Guanabenz (*Wytensin*) is similar to clonidine in effectiveness and adverse effects (*Medical Letter*, 25:11, 1983).

Guanfacine (*Tenex* - *Medical Letter*, 29:49, 1987) is as effective as other central sympatholytic drugs but has a longer duration of action, permitting once-daily therapy for most patients. Adverse effects are similar to those with clonidine, but tend to be milder.

DIRECT VASODILATORS — Direct vasodilators decrease diastolic and systolic pressures and cause little orthostatic hypotension.

Hydralazine (*Apresoline*; and others) is often given with a beta-blocker or a centrally acting drug to minimize the reflex increase in heart rate and cardiac output, and with a diuretic to avoid sodium and water retention. Diastolic pressure is decreased more than systolic when hydralazine is used alone. Maintenance dosage should be limited to 200 mg per day to decrease the possibility of a lupus-like reaction.

Minoxidil (*Loniten*; and others) should be reserved for hypertension refractory to other drugs. It can cause severe fluid retention and occasionally a pericardial effusion that rarely progresses to tamponade. Minoxidil must be used with a diuretic and is usually also given with a beta-blocker to prevent tachycardia and increased myocardial workload.

COMBINATION PRODUCTS — Many antihypertensive drugs are available in fixed-dose combinations, usually with a diuretic. Medical Letter consultants do not recommend beginning therapy with any fixed-dose combination, preferring to adjust the dosage of each drug separately. When two or more drugs are needed and the optimum maintenance doses correspond to the ratio in a combination product, there is no harm in using the combination, and taking fewer tablets may improve compliance in some patients.

INTERACTIONS — In addition to the adverse effects listed in the table, antihypertensive drugs may interact adversely with other drugs taken at the same time (*The Medical Letter Handbook of Adverse Drug Interactions*, 1989). One particularly important interaction can occur with nonsteroidal anti-inflammatory drugs (NSAIDs), which can decrease the effectiveness of many antihypertensive agents, but apparently not calcium-entry blockers.

Letter to the Editor

GOOD DOCTORS IN CHARGE

To the Editor: I enjoy your page each month "Reflections on Medicine." The September issue of *Connecticut Medicine* was especially welcome since you touched on so many points that need to be reemphasized especially to the younger generation in medicine who must question some and occasionally all of the values once fiercely held by the profession.

I vividly recall attending a meeting at the Mass Eye and Ear years ago at which time Dr. Leroy Schall, the Director, was most emphatic when he declared that in the care of the patient we should first do no harm. In this day and age the emphasis on material gains or glory affects many in the business, political, and even the educational field. Although we perceive this same trend affecting many in medicine I feel that the vast majority of physicians are primarily interested in only one thing, the care of the patient.

The proper selection of applicants to medical school and the emphasis on the basic values during their training should help to sustain these beliefs. Good doctors can do this and they should be in charge.

Timothy L. Curran, M.D.

West Hartford



Vice President, Medical Affairs

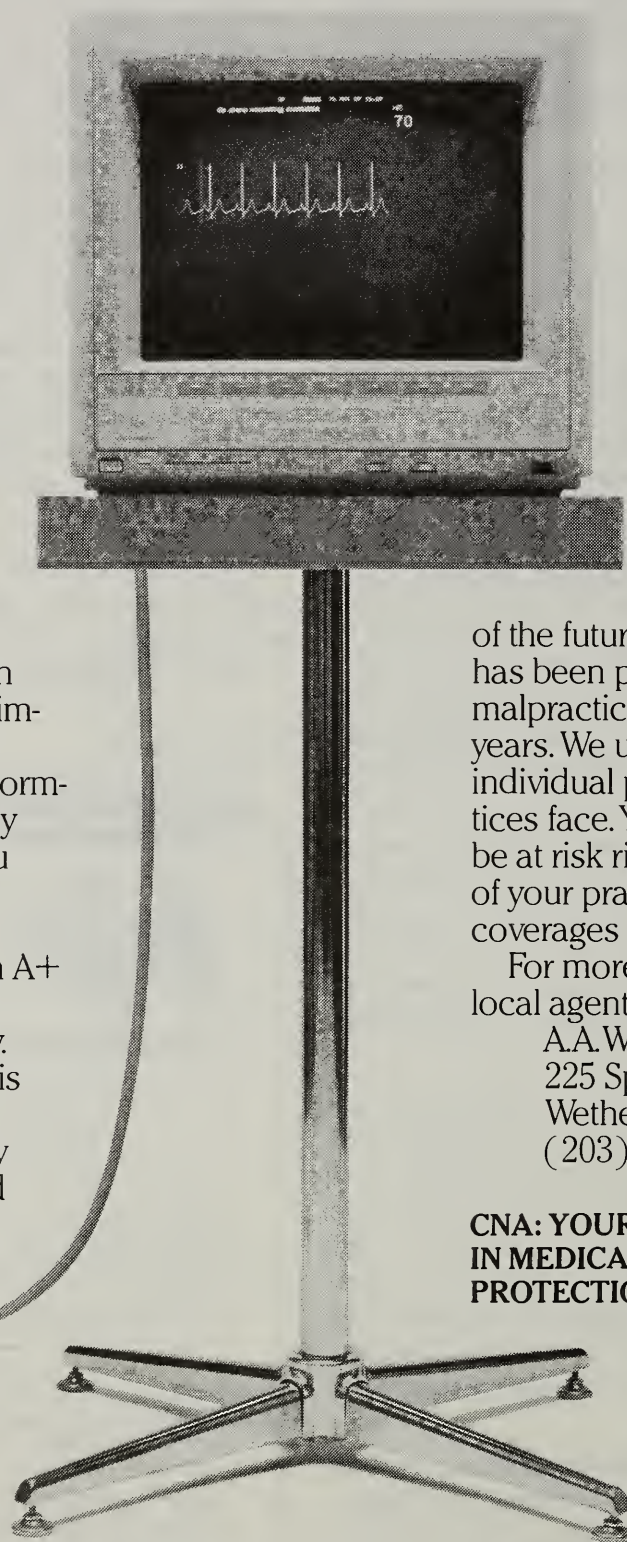
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The Latest Beef Over Cholesterol

According to health statistics, cardiovascular disease is this country's leading killer, responsible for nearly one out of every two deaths in the United States each year.¹ In the breakdown of cardiovascular deaths, coronary disease accounts for the majority (53% in 1986).¹

The three major, modifiable risk factors that have been linked to premature mortality from coronary disease are cigarette smoking, hypertension and hypercholesterolemia. There is little scientific argument or public debate over the merits of controlling the first two of these. And until recently, there was little debate in the public domain as to the wisdom of detecting and treating elevated cholesterol in adults. However, Thomas J. Moore's cynical critique of the National Cholesterol Education Program (NCEP), entitled, "The Cholesterol Myth," that recently appeared in *Atlantic Monthly*² stridently challenges the foundations of the NCEP along with its recommendations.

Given *Atlantic Monthly's* wide circulation and general respectability, the distortion of facts and notable omissions in Mr. Moore's article are unfortunate. For example, Moore criticizes lipid experts Daniel Steinberg, Scott M. Grundy and Antonio M. Gotto for failing to ask or answer the "important and basic questions" about cholesterol. In fact, these physician scientists, respectively, principal investigator of the Lipid Research Clinics Coronary Primary Prevention Trial,³ chairman of the dietary panel of the NCEP, and head of the Lipid Research Clinic at Baylor, have devoted virtually their entire academic careers to asking and answering the "important and basic questions" about cholesterol.

Moore alludes to a conspiracy of the "medical elite" that includes the cholesterol researchers, the pharmaceutical manufacturers and the American Medical Association. He implies that the cholesterol researchers are tainted because they accept research funding from pharmaceutical manufacturers.² But for new drug approval, pharmaceutical manufacturers must submit safety and efficacy data to the FDA. It is understandable and probably desirable that drug manufacturers look to reputable laboratories to carry out the requisite studies. Moore implies that the manufacturers are greedy because they strive to advertise and sell their cholesterol lowering agents.² Yet it is irrational to expect publicly-held corporations that spend millions of dollars in the development of new products to eschew advertising and marketing them. And Moore also implies that the American Medi-

cal Association is greedy in its support of NCEP's guidelines, which would encourage patients who "either have no personal physician, or have not seen their doctor within the past five years" to see a physician.² But, for the AMA to encourage adults to see a physician at least once in five years can hardly be considered greedy.

Moore fails to discuss the important results of the Cholesterol Lowering Atherosclerosis Study (CLAS).⁴ In a cohort of 162 men with cholesterol levels from 4.81 to 9.10 mmol/L (185 to 350 mg/dl) who had undergone coronary bypass grafting, CLAS demonstrated that atherosclerosis progression after two years was significantly less in the group treated with two drugs (colestipol and niacin) compared to the group treated with diet alone. Furthermore, in CLAS, there was evidence of regression in 16% of the coronary arteries in subjects treated with drug therapy.⁴

Results of other key studies^{5,6} that demonstrate benefit from cholesterol lowering are omitted in the *Atlantic Monthly* article as well. Overall, the American Heart Association's dismissal of Moore's essay as "more a polemic designed to support a preconceived notion of the author than an objective analysis of the available facts"⁷ appears to be right on the mark. It is unfortunate that hypercholesterolemic patients reading Moore's article will have grounds to rationalize their noncompliance with dietary modification and cholesterol-lowering medications.

Although Moore's condemnation of the NCEP can, from a scientific standpoint, be largely dismissed as nugatory, there remain a number of scientifically contentious issues that revolve around the rationale for the NCEP's recommendations. Three areas of major concern are discussed.

1. *The failure of prospective trials to demonstrate a reduction in total mortality.* Although coronary mortality was reduced 34% (8) and 19% (3) in two major cholesterol-lowering studies, no prospective, randomized trial has demonstrated a reduction in total mortality. The failure to reduce overall mortality stems from the fact that cholesterol lowering reduces the incidence of death only from coronary disease, which accounts for slightly under 25 percent of total deaths in the United States.¹ Thus, to achieve a statistically significant reduction in total mortality when the intervention (cholesterol-lowering) impacts on only one fourth of the total endpoints would require a trial of prohibitive size and scope.

2. *One mathematical model suggested only a minimal prolongation of life through lowering of cholesterol.* In an often-quoted article that recently appeared in the *Annals of Internal Medicine*, Taylor et al⁹ calculated that

the expected increase in life expectancy would be minimal (18 days to 12 months) when cholesterol was lowered by diet in hypercholesterolemic individuals. As a result, some physicians have questioned the rationale for dietary modification in their patients with high cholesterol levels. However, in their mathematical model, Taylor et al assumed a reduction in total cholesterol of only 6.7% through dietary changes,⁹ whereas motivated patients can often achieve substantially better results.¹⁰ In another model in the same article, when a 20% reduction in cholesterol was assumed for a 40 year old hypercholesterolemic patient, they projected a greater prolongation of life—approximately two years.⁹

Taylor's model failed to address nonfatal coronary events: acute myocardial infarction, stable or unstable angina pectoris or ischemic cardiomyopathy were not considered. Since cholesterol lowering has been proven to reduce the risk of these outcomes,^{3,8} the expected increase in the *event-free* survival would be greater than the increase in life expectancy alone. Thus, Taylor's model is limited, and a mathematical model that incorporates quality-of-life issues would be a more appropriate one to use in assessing the impact of cholesterol lowering.

3. *Questions about the accuracy of single cholesterol determinations.* Since cholesterol values in individual patients vary from day to day (with a standard deviation of 0.46 mmol/L (18 mg/dl) for total cholesterol¹¹ and 0.39 mmol/L (15 mg/dl) for LDL cholesterol),¹² and since the accuracy of cholesterol measurements have been questioned² critics of the NCEP have questioned the reliance on a single cholesterol determination as a basis for an entire therapeutic strategy. However, recognizing these pitfalls, the NCEP recommends using the average of two (or even three) separate cholesterol (or LDL) measurements to determine levels before initiating dietary or drug therapy.¹⁰

In addition, physicians should determine how well their local laboratory fares in the blinded testing of standardized cholesterol samples available from the CDC Core Lipid Laboratory or from the American College of Pathology. If the results are not satisfactory, cholesterol samples should be sent elsewhere.

These three legitimate areas of concern and others will continue to spark scientific debate as to how aggressive physicians should be in their attack on cholesterol. Should we screen for hypercholesterolemia in the asymptomatic elderly? Should we attempt pharmacologically to

increase a very low HDL level in a patient with a strong family history of coronary disease when the LDL cholesterol is acceptable? The answers to these and other questions are currently unknown, but will be undoubtedly addressed in future scientific investigation.

The recommendations of the NCEP are based upon a "preponderance of scientific evidence"⁷ demonstrating that cholesterol-lowering reduces the risk of coronary artery disease. The "stew" over the NCEP guidelines that Moore created by his *Atlantic Monthly* article² is thin and lacking in substance. While there may be a legitimate "beef" with some of the issues involving cholesterol, the NCEP recommendations,¹⁰ provide very reasonable diagnostic and therapeutic guidelines for the management of hypercholesterolemia.

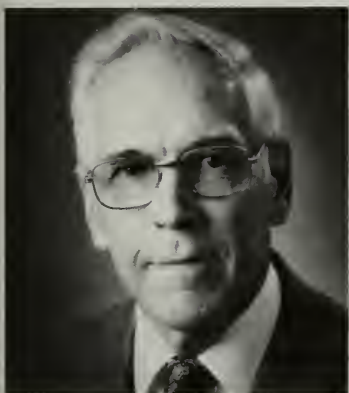
Peter Schulman, M.D.

University of Connecticut School of Medicine
Farmington

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Is Rationing in Our Future?



The control of the high costs of health care has become a national priority. Demands are heard on all sides that these costs be contained. The Congress and Federal budget makers will no longer tolerate Medicare expenditures in excess of \$500 billion per year. Corporate leaders argue that expensive employee medical insurance disadvantages them in competitive international markets. Everyone complains about hospital and doctor bills.

Controlling costs has not been easy in the complex, labor intensive, high technology world of health care. Major efforts now are directed to limiting supply, limiting demand, or a combination of the two, and improving efficiency in the delivery of care. In Connecticut the governmental approach has been to limit supply through regulation. The Commission on Hospitals and Health Care (CHHC) annually reviews each hospital budget and limits the introduction of any new service or

expensive technology through a Certificate of Need process.

To limit demand for health care services has been the method tried by competing insurance companies and HMOs in the State. You feel this in your practice as you contend now with pre-admission certification, same day surgical admissions, utilization review to shorten length of stay, emphasis on out-patient care, and questions about your diagnosis or treatment plan among others. Major corporations, in renegotiating labor contracts, are shifting more of the cost of health care to employees to reduce demand.

Medicare administrators are attacking the high cost problem in both ways. Hospitals are being squeezed and some forced to close since Medicare payments cover less than 70 cents on the dollar of hospital costs. Physicians are being harassed with rules and regulations like those listed above plus criteria for performing certain procedures and the added threat of retrospective denials for payment. Fees will soon be adjusted and reduced using the oft-discussed Resource Based Relative Value Scale.

Despite these many initiatives the cost of health care remains high. The Canadian Health System has been publicized widely as a model to be studied but many fear further Federal interference in their health care. Now, rationing of health care is being discussed openly as, perhaps, another option.

The statement has been made that we have always had rationing and always will. The only change is that we are now talking about it. Historically health care has not been as available to the underprivileged. Access was limited by the ability to pay. More recently, National Health Systems have reduced supply - fewer hospital beds, fewer physicians, less technology. Long delays and time spent in waiting lines or on lists became the currency of access. Our concern that all have equal access and our unwillingness in this country to wait for needed health care make this irrational form of rationing no longer acceptable. Now planned rationing is the law in Oregon and other states are considering similar actions.

Are the high costs of health care and our seeming inability to control them forcing us to consider rationing? The idea is repugnant to many of us. Can we not afford to give our citizens all the care medical science can offer; what are our national priorities? Have we, as providers, done everything possible to assure efficient delivery of care; what about outcome studies and practice guidelines? If rationing is necessary; what will be done and by whom? The list of questions is almost endless. Nonetheless, physicians must be involved in any discussions about rationing.

There is one certainty - physicians can not deny their individual patients needed care to control health care costs.

Roger S. Beck, M.D.
President

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Opportunity Fleeting; Judgment Difficult

ROBERT U. MASSEY, M.D.

Last month the MacNeil-Lehrer news hour ran a special feature on the overcrowding of hospital emergency services and used clogged Los Angeles emergency rooms to illustrate the problem. They showed ERs closed to new admissions for hours at a time to allow their staffs to manage the patients already jammed into their cubicles. Some were closed altogether because their hospitals had found it impossible to support services for which most patients were unable to pay. I have no idea how widespread this problem is, although I suspect it is not limited to Los Angeles. Even if it were, the portent is clear. When systems fail they first come apart bit by bit, wherever there is weakness, whenever pressures are greatest, but in the end the unraveling threatens the whole. A medical care system that has evolved, as ours has during the past 25 years, along a path of "disjointed incrementalism"¹ may now be gravely threatened not only by uncontrollable costs and by the unplanned-for growth in the numbers of infirm elderly but by the unexpected AIDS and drug epidemics, whose costs are loaded unto the hospitals.

Crises in medicine occur with almost predictable regularity, like the crashes of the Dow. Anyone reading the medical and political rhetoric of the last 100 years would observe that crisis fuses with crisis like the thunder of a summer storm. Yet this time there is a concatenation of epidemiologic, demographic, technologic, political, and economic forces that will require comprehensive rather than incremental reform. This is not easy in America where our system of government is designed expressly and wisely to move slowly, allowing time for deliberation as well as time for crises to fade away, resolving themselves, just as diseases usually do. Democracy is an internist, not a surgeon.

But surely surgery is called for when essential health services break down. When emergency rooms close for the 23-year-old male overdosed on crack, they are closed for the ten-year-old struck by a truck, or the 43-year-old with a myocardial infarction. Legislators faced with stubborn deficits and resistance to more taxation, already trying to deal with a drug war, a crisis in education, a deteriorating environment, and a gnatty swarm of

special interest groups have little stomach for taking on a 600 billion dollar enterprise. If they ever were in doubt about that, the consequences of their messing with catastrophic health insurance for the elderly has taught them that tinkering with appearances will no longer work. This may now be a rare opening for medicine—physicians, nurses, hospitals, medical schools, all those who understand and are worried about the problems—to assume a leadership position, joining with corporate leaders and government statesmen to work out a plan that is more than a quick fix, more than "disjointed incrementalism." The National Leadership Commission on Health Care is just such a group, voluntarily formed in 1986 and now hard at work on its comprehensive, quite typically American proposal. (see pp. 659-64)

No proposal that requires systemic changes, including universal health insurance (not federal, or national), reduction of unnecessary care, cost sharing, expanded biomedical research, and malpractice reform, will satisfy everyone; we may, however, have to forego our national pastime of talking everything to death and get on with the job, beginning with this or some similar plan.

The National Leadership Commission has made an admirable start, but it may yet require an earthshaking crisis to get our attention; emergency rooms closing around the country may do it. "Let some bigwig have a heart attack," remarked an ER physician, "and be turned away from his favorite hospital, and die—that might do it!" A rise in health care costs to 13% of the GNP might do it, or a doubling of AIDS patients in our hospitals over the next 18 months would concentrate our minds wonderfully. One can imagine any number of wild-eyed schemes for reform, schemes that would attend to costs only, or to corporate profits, or union benefits, proposing anything to get the doctors or punish the hospitals. An aroused public can be angry and our legislators dangerous; the Commission's plan is a place to start, a *via media*, and medical societies should be leading the discussion and lighting the way for our political masters.

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ROBERT U. MASSEY, M.D., Professor, Division of Humanistic Studies in Medicine, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.

50 Years Ago
From the *Journal of the Connecticut State Medical Society*
November 1939

Modes of Transmission in Poliomyelitis*

JAMES D. TRASK, M.D.,
New Haven, CT

The natural mode of transmission of poliomyelitis is unknown and, consequently, discussion of it is apt to be lengthy.

However, some remarks may be made which, I trust, are pertinent. Today the dogma of the nasal portal of infection seems to be adhered to less rigidly than was the case a few years ago. At any rate, authorities are ready to admit that besides the nose, there may be other avenues to the central nervous system and there is not much eagerness for chemical prophylaxis by the nasal drops. This may be considered an advance because the characteristic seasonal incidence of poliomyelitis does not fit well with the idea of a nasal disease.

The changing opinion about the portal of entry depends on a number of disconnected observations which concern: (1) the natural disease in man; (2) experimental poliomyelitis in man and in animals; and (3) the distribution of the virus in nature.

1. Lesions are not found in the olfactory bulbs in fatal human cases.

2. (a) The disease has been produced accidentally in man by the subcutaneous inoculation of vaccine; and

(b) Bulbar poliomyelitis occurs as a rare but characteristic sequel 7 to 10 days after tonsilectomy.

(c) The experimental disease in monkeys may follow almost any method of administration of virus; intranasal instillation; intracutaneous, subcutaneous, intraperitoneal and intraneural inoculation. Especially important is the fact that monkeys may be infected by placing virus in their food. In America we were slow in believing this, because for oral infection it is necessary to use other monkeys than the common rhesus.

3. Finally, it is easier to detect virus in the stools than in the nasal washings of patients and convalescents; and it may persist in their stools for weeks after even mild and abortive poliomyelitis. The virus is highly resistant in stools and when kept in the refrigerator may remain active for 2½ months. Twice we have found virus in stools sent by mail from England. Dr. Paul, Dr. Culotta, Dr. Gard and myself have found virus in large amounts in sewage in the two recent epidemics in this country.

In reviewing the last finding one must admit that it may tell us nothing of how the virus is actually transmitted, but it demonstrates the existence of an enormous natural reservoir.

*Read at the 15th Clinical Congress, Connecticut State Medical Society, New Haven, September 19-21, 1939.

This five-minute talk was the first public announcement of a discovery made by Dr. Trask, Dr. John R. Paul, and their associates as a result of their work at the Yale University School of Medicine with the aid of grants from the President's Birthday Ball Commission for Infantile Paralysis Research.—Ed.

LUCA E. H. CELENTANO, M.D.

1900 - 1989



Dr. Luca E. Celentano, my friend and long time associate, died on 1 September, 1989, in New Haven, the city of his birth, where he had been prominent in the general practice of medicine for 57 years.

Dr. Celentano, first son of Italian immigrants, graduated from New Haven's Hillhouse High in 1918. He was admitted to Trinity College, Hartford, after serving in the U.S. Army during World War I. He matriculated at Harvard Dental School, but then opted for a career in medicine. He received his M.D. from Hahnemann Medical College, Philadelphia, in 1930, then returned to New Haven where he interned at Grace Hospital, now Yale-New Haven. In 1932, he began his private practice.

For the better part of six decades, Dr. Celentano worked hard practicing his craft. From home deliveries, kitchen table tonsillectomies, service as a Naval Medical Commander in World War II, to caring for the poor, the sick, and the dying, this classic "old school" physician served his community with honor, astute medical acumen, and dignity. Communication with everyone was paramount to his success.

Dr. Celentano's professional accomplishments and accolades, in reality, are too numerous to mention. He was a living legend in New Haven, an active practitioner since 1932 at all local hospitals, and medical director of several area nursing homes. He was chairman of the New Haven Board of Health for the better part of 20 years, as well as president of the New Haven Police Commission. He was a governor of the New Haven City and County Medical Association, and former president of both. He served in the Connecticut State Medical Society's House of Delegates. At one time, he was even asked to run for lieutenant governor of our state. He was president à vie of the Cabinet, the historical "invisible hand" of the New Haven Medical Association.

In his later years, Dr. Celentano was a sought-after philanthropist; his contributions to many local charities and institutions constantly making news. Numerous scholarships and buildings bear his name. In 1988 the Hospital of St. Raphael dedicated its massive new wing in his honor. Interestingly, the site of this building is on the block where Dr. Celentano once delivered groceries as a boy.

Besides his wife, Jean Hippolitus Celentano, herself a physician who in 1925 was among the first women to graduate from Yale University School of Medicine, Dr. Celentano is survived by his sister, Ellen E. Celentano. He is predeceased by his brothers, former New Haven Mayor William C. Celentano, and Alfred F. Celentano, and a sister, Adelaide Celentano.

Revered by contemporaries, associates, and patients for his wit and humor, common sense approach to medicine and life, compassion and kindness and coupled with his generosity of time, talent, and treasure, Dr. Celentano has earned a place as one of Connecticut's premier physicians. Thoreau once said, "the laws of the Universe are forever on the side of the most sensitive"; truth, indeed, as Luc was blessed with good health for many years, and had a great zest for life. In death, however, his contributions to medicine, the community, and his patients will never be forgotten; nor will his trademark red bow-ties. Most certainly, "Dr. C" will be missed by all who knew and loved him—his entropy to continuously increase....

New Haven

Alfred J. Ranieri, Jr., M.D.

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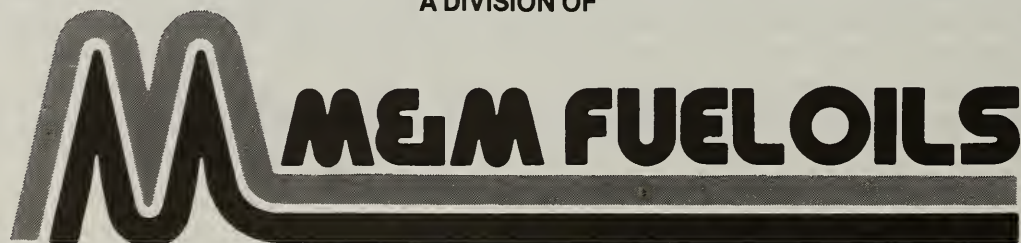
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From the Executive Director's Office

COUNCIL MEETING

Thursday, October 19, 1989

Attendance

Present in addition to the Chairman, Dr. Joseph C. Czarsty were Drs. Ahamed, Beck, Blum, Bobruff, Bonner, Dardick, Eslami, Freedman, Hollister, Jr., Kamens, Kaufmann, Keating, McDonnell, Orphanos, Petrie, Redmond, Reyelt, Jr., Robbins, Sosa, Zanker and Zeppieri.

Also present: Mr. Norbeck, Mrs. Lindquist, Mr. Brunell, Mr. Sullivan, Ms. Ballou, Marc Sullivan, Mr. Tomat (FCMA), and Mr. Coffey (HCMA).

Absent were: Drs. Catrini, Chmieski, Fox, Lesnik, Meridy, Parikh, Petro, Rose, Sadowski, Welch, Wetstone, Zlotzky, and Mrs. Reed.

Report of the President

County Meetings: Dr. Beck reported that, to date, he had attended the Hartford, Litchfield, and Fairfield county meetings and at each meeting he reported on CMIC, M.D. Health Plan, and the CSMS purchasing Plan. He also spoke on image building for physicians and some of the activities CSMS has been undertaking and the attempts being made, especially through the Legislative Committee, to develop a sense of unity within the profession and the specialty sections. He expects to attend most of the other county meetings.

Department on Aging: Dr. Beck discussed a meeting held, at the request of the Council, with Commissioner Klinck, Deputy Commissioner Bell of the Department on Aging, and members of the CSMS staff concerning the progress being made in the courtesy card program which was taken over, by law, by the DOA. He reported that it was a productive meeting and that at the time the Department took over the program there were 79,000 members in the program and now there are 83,000 members and the program has been renamed ConnMAP. It was reported that there was some effort being made to promote the program, but the ConnPACE program, the prescription drug program, which has lower eligibility limits, has been receiving greater attention and more people have been signing up for that program than the ConnMAP program. It was stated that the best way to promote the ConnMAP program was through physicians' offices and the DOA has agreed to supply literature for that purpose.

He also discussed with members of the DOA the proposed bag program for senior citizens in which they could collect all their medications to bring to their family physician. Commissioner Klinck informed the group that the Pharmaceutical Association is involved in a similar program and that if the program is undertaken, perhaps it can be coordinated with them and be imple-

mented through the Academy of Family Practice and the Society of Internal Medicine. The concept of this program was referred to the Committee on Public Affairs for consideration and report back to the Council with recommendations including financial notes on any proposals.

The representatives of the DOA expressed the opinion that an all-out effort will probably be made this year by the AARP for mandatory assignment.

Appointments: Dr. Beck reported that the following appointments had been made: Neil Brooks, M.D., Rockville, will represent CSMS on the Advanced Practice Registered Nurses' Regulatory Program. Stephen O'Brien, M.D., Enfield, will represent CSMS on the *ad hoc* committee that was created by the Department of Health Services to submit recommendations for legislation on the licensure of physician assistants and prescriptive authority to the Public Health Committee.

Report of the Executive Director

Tim Norbeck reported on the following items:

- (1) He gave an update on the catastrophic bill which had been repealed by the U.S. House of Representatives 360-66 on October 4th. The Senate voted 99-0 on October 6th to repeal the surtax portion but retained the unlimited hospital coverage. Negotiators for the House and Senate will attempt to reconcile the different approaches. He further reported that it was easy to predict the inevitable backlash once seniors realized their surtax obligation under the original bill, and just as easy to predict another backlash from the sixty percent who would not owe any surtax, should the bill be entirely repealed. He stated that this would be a major issue in the 1990 elections.
- (2) Mr. Norbeck also indicated again that the struggle against mandatory assignment would be most difficult in 1990. The AARP facing criticism from many of its chapters because of the catastrophic bill, will undoubtedly lend its full support to mandatory assignment proponents.

Nomination to Board of Director of CSMS-IPA

A communication was received requesting that CSMS furnish a replacement, from Hartford County, to fill the balance of the term of Richard Stone, M.D., Bloomfield, which runs until May 1990. The name of a replacement will be submitted by Hartford County and forwarded to the IPA Board of Directors.

Resignation of Alternate Delegate to AMA

It was VOTED to accept with regret the resignation of Robert M. Chmieski, M.D., as Alternate Delegate to AMA.

Nomination of AMA Delegates

It was VOTED, by acclamation, to make the following changes in the AMA delegation:

Jerome Bobruff, M.D., New London, AMA Alternate Delegate, was elected AMA Delegate to fill the unexpired term of Vincent J. Catrini, Middletown, who resigned.

John B. Franklin, M.D., Hartford, was elected AMA Alternate Delegate to replace Robert M. Chmielecki, M.D., Bristol, who resigned.

Neil H. Brooks, M.D., Rockville, was elected AMA Alternate Delegate to replace Jerome Bobruff, M.D., New London, who was named AMA Delegate.

Howard W. Meridy, M.D., Torrington, was named to temporarily fill in as AMA Alternate Delegate in place of Annemarie S. Welch, M.D., who will not attend the AMA December meeting.

Report of Fiscal Subcommittee:

The Council took the following action on the report of the Fiscal Subcommittee:

- (1) *1990 Budget*-Following review and discussion, it was VOTED to approve the 1990 Budget as presented by the Fiscal Subcommittee, and transmit it to the House of Delegates on November 15, 1989, with the Council's recommendation that the budget be approved and that the CSMS dues remain at \$300.00.
- (2) *Charitable Trust*: VOTED unanimously to add a line item on the dues bills of \$25.00 which would be listed as voluntary contribution.
- (3) *Dues Policy*: VOTED to confirm policy that physicians, not newly in practice, who become members in the spring pay full years dues, and that members, now newly in practice, who become members in the fall, pay one-half years dues.

Report on CMMI and CMIC Activities

It was VOTED to receive as information a report on CMMI, Inc. by Mehdi Eslami, M.D., Chairman. The report outlined membership growth, premium decrease, financial information, and number of claims received.

It was further VOTED that the majority of the members of the CMMI Board may not serve as members of the CMIC Board.

CSMS Annual Scientific Program

Dr. Beck brought to the attention of the Council comments that he had received concerning the poor attendance at the general scientific program which was held during the annual meeting. He reported that he had discussed this problem with the Chairman of the Program of the Scientific Assembly and learned that several different formats have been tried to encourage attendance without success. Following discussion, it was VOTED to discontinue the general scientific program for 1990. It was further VOTED that a committee be appointed to study the subject. Edward Kamens, M.D., was named chairman of the committee.

Report from Committee on Allied Health:

In accordance with the Council's request, the Committee on Allied Health met with the President of the Connecticut Chapter of the American Physical Therapist Association regarding licensure and direct access of patients. The committee submitted a proposed letter to legislators which sets forth ideas which would be helpful in combating another attempt by the physical therapists to gain direct access to patients. It was VOTED to approve the concept outlined in the proposed letter to legislators.

Committee on Legislation

It was VOTED approve the following recommendations which appeared in the minutes of the Committee on Legislation:

- (a) That any legislation concerning mandatory assignment be opposed.
- (b) That CSMS oppose any attempts by allied health professionals to gain direct access to patients.
- (c) That CSMS oppose any attempts to limit a physician's right to charge interest on overdue bills.

Liaison Committee with Connecticut Bar Association

At the June meeting of the Council on Ad Hoc Committee was appointed to review the charge and organization of the Liaison Committee with the Connecticut Bar Association. Stewart J. Petrie, M.D., Chairman of the *Ad Hoc* Study Committee submitted a report of the committee which included several suggestions and it was VOTED to approve Item 7 of the report which outlined the charge to the Liaison Committee which reads as follows:

"The *Ad Hoc* Liaison Committee with the State Bar Association should deal with matters of mutual concern between CSMS and the Connecticut State Bar Association. An agenda shall be prepared in coordination with the counterpart of the Connecticut State Bar Association. Such agenda to include such items as management of record requests, court appearances, tort reform and other matters they may present themselves."

Dr. Petrie suggested that a copy of the report be forwarded to Philip Shelton, M.D., Chairman of the Liaison Committee with the Connecticut Bar Association.

Committee to Meet with Workers' Compensation Commissioner

At the annual meeting of the House of Delegates, a letter mailed to all physicians by the State of Connecticut Workers' Compensation Commission, concerning the implementation of Section 31-294 of the Connecticut General Statutes providing for an approved list of physicians furnishing medical services in workers' compensation cases, was referred to the Council for study, consideration and action.

This subject was referred to an *Ad Hoc* Committee for study and Joseph Zeppieri, M.D., Chairman, reported

to the Council that representatives of CSMS and State Commissioner of Workers' Compensation, John Arcudi, and several other commissioners met on September 28 to discuss the issue. It was stated that physicians were not knowledgeable of their responsibilities in the workers' compensation system and were not aware of how their patients suffered from unnecessary long term disability. They also stated that from the time the law was enacted in 1967, Connecticut Statutes have required the Commissioner to establish an approved list of providers. Political pressure has now been placed on the Commissioner to develop such a list and physicians have been requested to indicate their willingness to become a part of this list. CSMS representatives indicated that CSMS is taking the position that the list should be made up of all licensed physicians.

There was discussion concerning the development of educational materials for the physicians outlining their role in getting their patients back to work, interacting

with the compensation commissioner, the insurance company and the employer. Dr. Zeppieri stated that he informed the commissioners that, for the last five years, organized medicine has been working with them on educational programs about the disabled worker. He reported that another meeting is planned to develop educational seminars and to continue the discussion relating to the provider list.

Life Members

It was VOTED to receive, as information, that Henry G. Cohen, M.D., Danbury, was granted Life Membership as of 1/1/90.

N.B. The foregoing is a summary of the proceedings and actions of the Council on October 19, 1989. Detailed minutes of the meetings are on file at 160 St. Ronan Street, New Haven, for perusal by any interested member of the Society.

November 16, 1989

Roger S. Beck, M.D.
President
The Connecticut State Medical Society
160 St. Ronan Street
New Haven, CT 06511

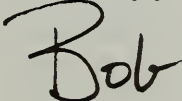
Dear Roger:

It has been distressing to me to discover that Mr. Ralph Pollock has implied, apparently in a public meeting, that I am a member, and perhaps even chairman, of the "Physician Advisory Board" of the Healthcare Purchasing Organization.

This implication is entirely false. It is true that on one occasion (10 August 1989) he and Mr. Daniel O'Connell at a luncheon meeting told me of their plan to set up this organization, and even asked whether I would consider serving in some capacity to advise them from time to time. I clearly and unambiguously declined, but did urge them to seek advice from others including members of the Hartford County Medical Association and the Connecticut State Medical Society as well as faculty members of the two schools.

I have asked Mr. Pollock to retract any statements he has made regarding my association with the Healthcare Purchasing Organization, in particular his implication that I am a member of the Advisory Board. I enclose a copy of my letter to him.

Sincerely yours,



Robert U. Massey, M.D.
Professor of Medicine and Community
Medicine and Health Care

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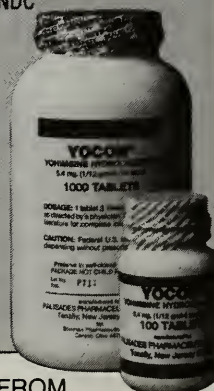
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- A. Morales et al., New England Journal of Medicine: 1221, November 12, 1981.
- Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
- Weekly Urological Clinical letter, 27:2, July 4, 1983.
- A. Morales et al., The Journal of Urology 128: 45-47, 1982.

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Executive Director's Office
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- ☐ Committee on Insurance

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Please Return by January 20, 1990

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The Society maintains the Physician Placement Service as a service to the medical profession in Connecticut. Opportunities for physicians to locate in Connecticut will be published as space permits and will be distributed to physicians making inquiries of such opportunities. Information should be sent to 160 St. Ronan St., New Haven, CT 06511 (203-865-0587).

Physicians wishing to establish practice in Connecticut are invited to submit a resume to be kept on file with the Society. An announcement of a physician's availability will be published in two issues of *Connecticut Medicine* as space permits.

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Busy Medical practice—Internal Medicine available due to untimely physician's death. Well-established; fully-equipped including x-ray facilities. Reasonable terms. Spanish language an asset. Call 335-4193, Bridgeport, CT.

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July '90. Age 31. Licensed in Connecticut. Nat'l bds. AB elig. MD, University of Autonoma of Guadalajara, Guadalajara, Jalisco. Int. and Res., University of Medicine and Dentistry of New Jersey, Newark. Prefers solo, group or associate type practice. Write, Craig R. Elliott, M.D., 55 Schuyler Ave., #17, North Arlington, NJ 07032.

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May '90. Age 44. Nat'l bds. AB cert. MD, New York Medical College, New York, NY; Int., Lenox Hill Hospital, New York, NY; Res., NY Medical College, New York, NY; Fellowship, Metropolitan Hospital Center, New York, NY. Prefers group or institutional type practice. Write, William Cristo, Jr., M.D., 12 Delafield Dr., Lenox, MA 01240.

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2. Kremer H, Kellner E, Schierl W, et al: Ultrasonic diagnosis in infiltrative gastrointestinal diseases. *Dtsch Med Wochenschr* 1978;103 (June 9): 965-966. Abstracted, *JAMA* 1978;240:2784.
3. Influenza vaccine—recommendations of the Public Health Service Advisory Committee on Immunization Practices. *MMWR* 1979;28:231-238.
4. Fischer DH: *Growing Old in America*. New York, Oxford University Press, 1977, pp 210-216.

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A Three-Year Report of the Medical Helicopter Transportation System of Connecticut

LENWORTH M. JACOBS, M.D., ROBERT J. SCHWARTZ, M.D.,
BARBARA BENNETT JACOBS, R.N., DANNY GONSALVES, M.S.,
AND SHERYL G. A. GABRAM, M.D.

Introduction

AS of April 1988 there were 154 hospital-based aeromedical helicopter programs in the United States. These programs accounted for 97,900 patient transports and over 13 million miles logged in 1987. An estimated 535,000 patient transports have been completed since the initial helicopter service became operational in 1972.¹ In 1985 Hartford Hospital initiated a critical-care helicopter system, LIFE STAR, to serve the state and nearby regions within a 150 mile radius. The concept of bringing highly educated and trained medical personnel directly to the scene of an injury or to another hospital is an important one, as these patients are at a greater risk of death or increased disability.²⁻⁶

The Connecticut aeromedical system is regional in scope and designed to be sensitive to patient and physician-referral patterns. In order to achieve these goals the state's Office of Emergency Medical Services (OEMS) regulates the oversight of the LIFE STAR system and also the designation of helicopter receiving hospitals within Connecticut. The LIFE STAR program is multidisciplinary with administrative, aviation, clinical, and research personnel. The helicopter staff includes pilots, physicians, flight nurses, and respiratory therapists. The medical crew configuration varies depending on the type of flight. During the past year, data from the research division demonstrated a need for a physician on scene flights, a concept studied by other programs.⁷⁻⁹ The medical crew configuration for a scene request consists of the emergency medical physician, flight nurse, and the respi-

ratory therapist. Interhospital transfers rarely require the physician unless special circumstances exist, ie, a neonatal, pediatric, or a critically unstable cardiac patient. Currently physicians are available for interhospital transfers when these circumstances arise. The emergency medicine physicians provide on-line medical control in the aircraft or via radio from the emergency department at Hartford Hospital.

Although medical protocols are utilized by the flight nurses, variations of these may be initiated through radio contact with the base station. Upon completion of the flight, the patient record is reviewed with the on-line physician responsible for issuing the orders. The LIFE STAR program was started with three pilots. In April 1988 a fourth pilot was added to the system because of an increased demand for flights. Crew education and certification requirements have been reported previously.¹⁰

System Evaluation

Five components of evaluation contribute to a comprehensive review and analysis of LIFE STAR operations: 1) a LIFE STAR registry, 2) an oversight committee, 3) individual case audits, 4) mortality and morbidity reviews, and 5) research and data analyses.

Before the LIFE STAR program became operational, planners designed a comprehensive data registry which records information beginning at the time of initial contact with the aeromedical system through the patient's discharge and final disposition. The registry garners data from the flight nurse's record, dispatch form, pilot's log, and medical record. By the establishment of this computerized data base registry, Hartford Hospital has assured the careful recording of aeromedical data and the quick retrieval and analysis of data. The registry assists in the decision-making process required in managing a complex system.¹¹

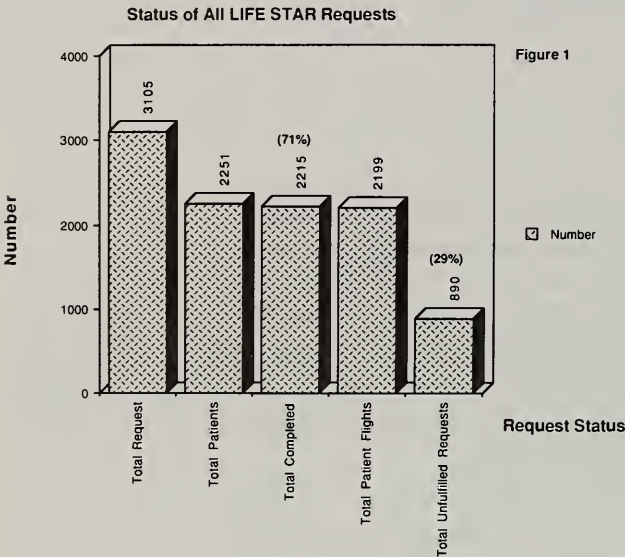
The end of 1988 marked the completion of over three and one-half years of successful operation of the system. This report summarizes this initial period of operation.

LENWORTH M. JACOBS, M.D., Director Department of EMS/Trauma, and Director LIFE STAR, Hartford Hospital; Professor of Surgery, University of Connecticut School of Medicine. ROBERT J. SCHWARTZ, M.D., Director of Research EMS/Trauma Department, Hartford Hospital. BARBARA BENNETT JACOBS, R.N., EMS/Research/Educator, Hartford Hospital. DANNY GONSALVES, M.S., Assistant Professor, Southern Connecticut State University, Southern. SHERYL G.A. GABRAM, M.D., Assistant Director LIFE STAR, Hartford Hospital.

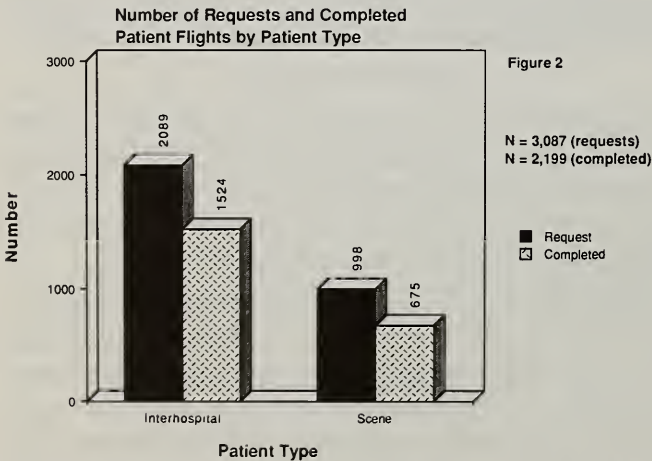
The data included in the tables and figures identify requests, completed flights, or completed patient flights, and other demographic elements of the program.

Results

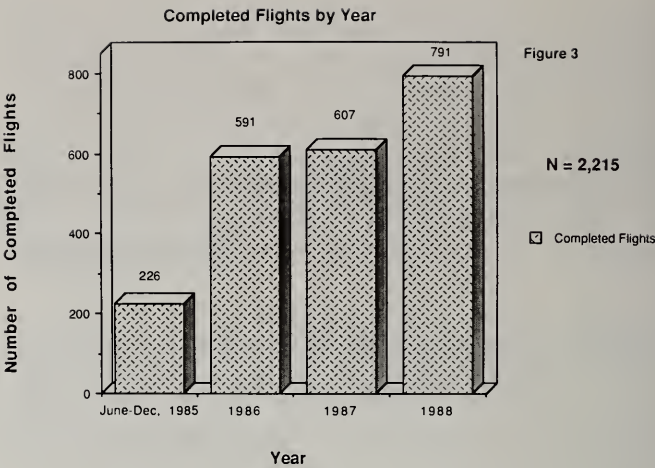
From the first LIFE STAR flight early on the morning of 18 June 1985 to 31 December 1988, approximately a three and one-half year period, 2,251 patients have been flown to medical facilities. The dispatch center received 3,105 flight requests. There have been 2,199 completed patient flights, as well as 13 organ transfers, two equipment transfers, and one flight involving a disaster drill for a total of 2,215 completed flights (Fig 1).



Seventy-one percent of all requests were completed. Of the completed requests 1,524 (68.8%) were interhospital flights and 675 (30.5%) were scene responses (Fig 2). Fifty-two of the completed patient flights (2.4%) involved

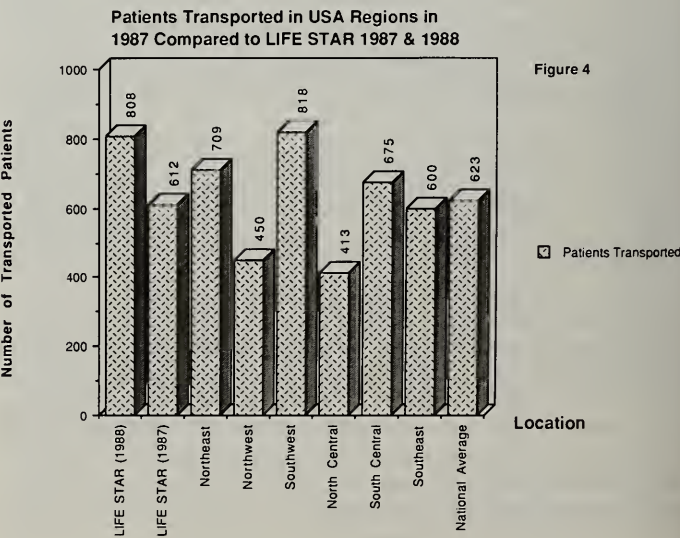


the transport of two patients in the aircraft. Of these 52 flights, 32 were scene responses and the other 20 transferred patients from one hospital to another. A comparison of the last three full calendar years of operation (1986, 1987, 1988) indicates a steady increase in utilization of the LIFE STAR system. Data indicate a 12.8% increase in total flight requests from 1986 to 1987, and a 27.7% increase from 1987 to 1988. Completed flights increased 2.7% from 1986 to 1987 and 29.5% from 1987 to 1988 (Fig 3).



During 1988, LIFE STAR completed 791 flights and transported 808 patients which compares favorably with the national average for 1987. The 1987 national average for patients transported was 623 and the northeastern average was 709 patients. The higher average for the southwestern region is in part a reflection of programs with more than one helicopter (Fig 4). The national data do contrast with LIFE STAR in that the Hartford Hospital based program flies more scene flights, 33%, (1988) than most programs in the eastern two-thirds of the United States.

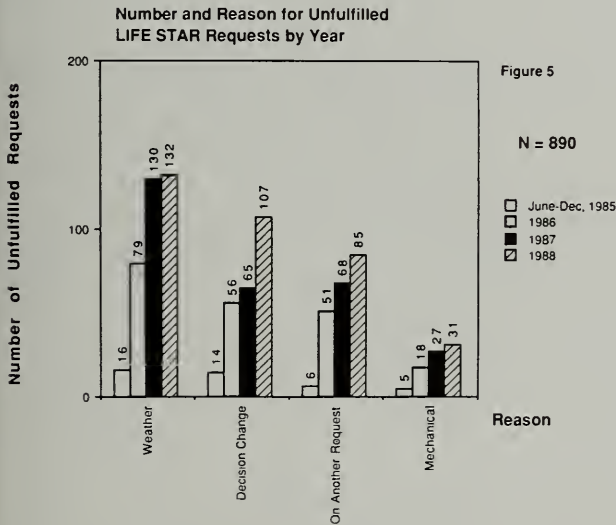
The 1988 average round trip distance for LIFE STAR was 73 nautical miles (nm). This is well below the national (106 nm) and northeastern (94 nm) averages. LIFE STAR completed a higher percentage of scene flights which tend to be shorter flights and it has operated in a densely populated, urban and suburban area of the country. The helicopter has flown over 162,000 nautical miles. It has served all six New England states plus New York, New Jersey, Pennsylvania, and Canada. Increasingly the service has expanded its geographical range by serving medical facilities farther from its home base. The longest flight, 462 nautical miles round trip, was an interhospital flight between the Royal Victoria Hospital in Montreal, Canada, and Hartford.



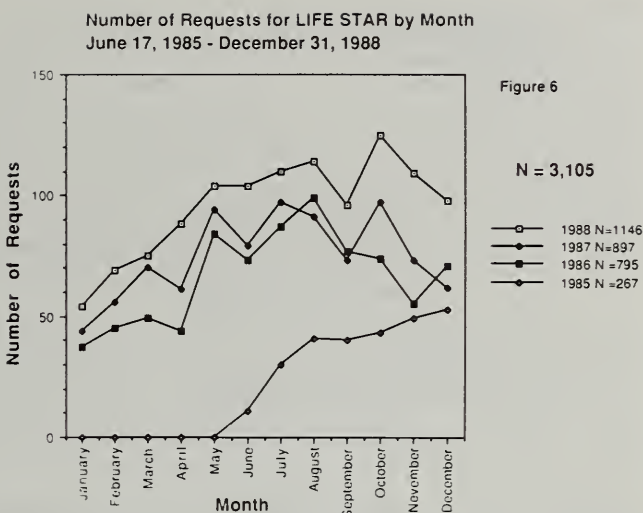
During the second half of 1988 there was a sharp increase in requests and completed flights. Sixty completed flights per month is generally considered the maximum for a single aircraft. Since March 1988 LIFE STAR has been exceeding this maximum. The 791 completed flights in 1988 exceed the national average (623) for single aircraft programs. The data suggest the need for system expansion by the addition of a second helicopter.

Unfulfilled Requests

Of the 3,105 requests for air transport received at the LIFE STAR Dispatch Center, 891 (28.7%) were not fulfilled for a number of reasons. Weather accounted for 357 (11.5%) of the uncompleted requests while 242 (7.8%) were cancelled because of a medical decision change. Examples of a medical decision change are the following: that basic life support (BLS) ground personnel decided to transport the patient after requesting LIFE STAR, that an interhospital transfer patient expired prior to LIFE STAR arriving at the transfer facility, that a BLS crew requested LIFE STAR at the scene of a crash but after arrival of an advanced life support (ALS) ground crew, the decision to transport by air was unwarranted as determined by the ALS crew, or that, after an initial request for an interhospital transfer was made, medical personnel in the transferring facility decided not to transfer.



Eighty-one requests (2.6%) had to be denied because of mechanical problems with the aircraft and 210 (6.8%) were denied because LIFE STAR was on another flight. Because the EMS communications network informs field EMS crews whenever LIFE STAR is on a mission, and since they can monitor the LIFE STAR radio frequencies, there are most likely more circumstances when LIFE STAR is indicated and a request is not generated. It is estimated that the total "missed request" rate (due to being on another flight) is at least one-third higher or an estimated 9% of all requests. The missed request frequency increased from 68 in 1987 to 85 in 1988 accounting for about 7.5% of all requests each year (Fig 5). Although unfilled requests due to a medical decision



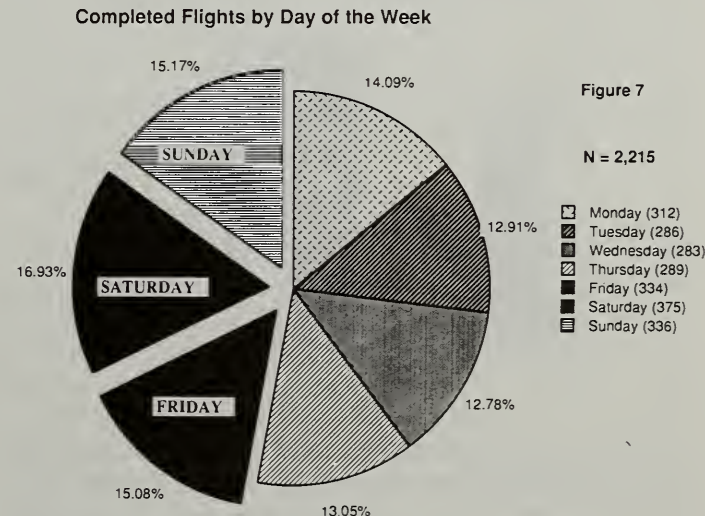
change have risen over the three-year history, such an increase is not objectionable since usually the decision not to fulfill the request is due to the patient's condition and therefore avoids an unnecessary response.

It would be useful to monitor the outcome of patients for whom air transport was requested but who were not eventually transferred. However, to date such a tracking system has not been developed and would require extensive interagency coordination, communication, and willingness to provide the data to the helicopter oversight committee.

Temporal Patterns

Utilization demonstrates a strong seasonal pattern, with the peak during the summer months of May through September (Fig 6). May and June of each of the three years reveal this sharp increase. Data on total requests and completed flights indicate a subsequent low utilization period during the winter months of January through March. This pattern reflects national trends that indicate a seasonal pattern to trauma.¹²⁻¹⁴

The system is busiest during the weekends, with Saturday being the peak day (Fig 7). The pattern of high volume vehicular traffic during the spring and summer weekends places larger numbers of people at risk for



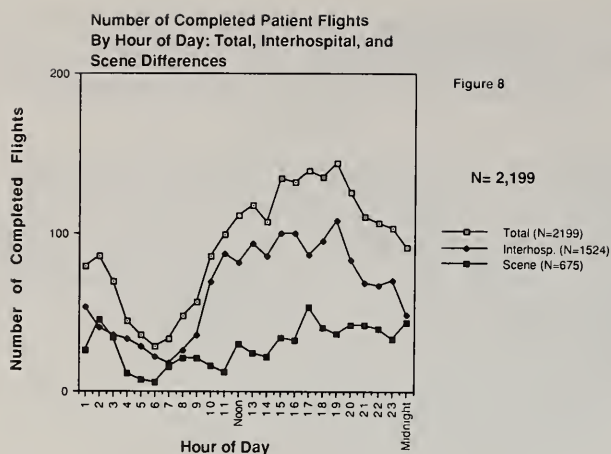


Figure 8

N = 2,199
 —○— Total (N=2199)
 —●— Interhosp. (N=1524)
 —■— Scene (N=675)

roadway trauma. Wednesday is the day with the least requests.

A third temporal pattern is the hour of day for requests. When flights are analyzed by the hour of the day, responses increase from about 2:00 PM onward to a peak at 5:00 PM and remains high until about 3:00 AM. The interhospital completed flights rise sharply after 7:00 AM to a peak at 7:00 PM after which there is a sharp decline (Fig 8). The temporal patterns of day and time also support the observed national trends.¹²⁻¹⁴

Types of Patients

The majority of the 2,251 patients transported were trauma patients (63%) and the remaining 37% had a variety of medical conditions. They were general medical conditions (16%), cardiac problems (12%), nontrauma pediatric patients (7%), neonatal crisis (1%), and high risk pregnant mothers (1%) (Fig 9). In response to scene requests, the crew transported a total of 702 patients with 643 (91.6%) being injured and only 59 (8.4%) having some type of nontraumatic or medical condition. Of the 702 scene patients, 394 (56.1%) were drivers or occupants of a motor vehicle. Motorcyclists accounted for 11.5% of scene trauma, pedestrians struck by vehicles were 5.4%, falls 4.2%, and bicyclists 2.4%.

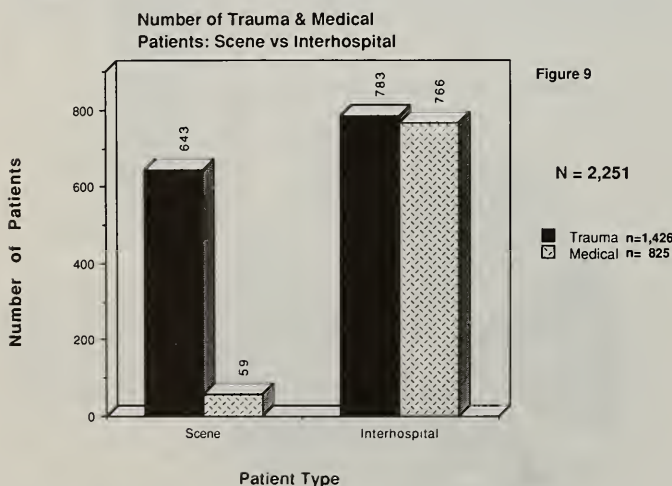


Figure 9

N = 2,251
 ■ Trauma n=1,426
 ▨ Medical n= 825

The location of sites where injuries occurred reveals a specific geographic pattern. Roadways are not the only location of scene calls. Of the 702 scene patients a total of 533 (75%) patients were injured on roadways. These

patients were injured either in a motor vehicle or on a motorcycle, or were pedestrians struck by a motor vehicle or motorcycle, or were struck by a vehicle while on a bicycle. Over 74% were in a motor vehicle while over 15% were on a motorcycle. Those scene responses not to roadways were to a combination of various types of buildings or dwellings, as well as other outdoor areas such as lakes, swimming pools, and parks.

Over 76% of all roadway injuries were on state undivided roads and municipal roads (assumed to be mostly undivided). National data also indicated that undivided highways are more dangerous than the newer, better designed and engineered divided roadways.¹³⁻¹⁴ This great a differential between undivided roadways and divided roadways may also be influenced by referral patterns of initial responders.

Request Patterns

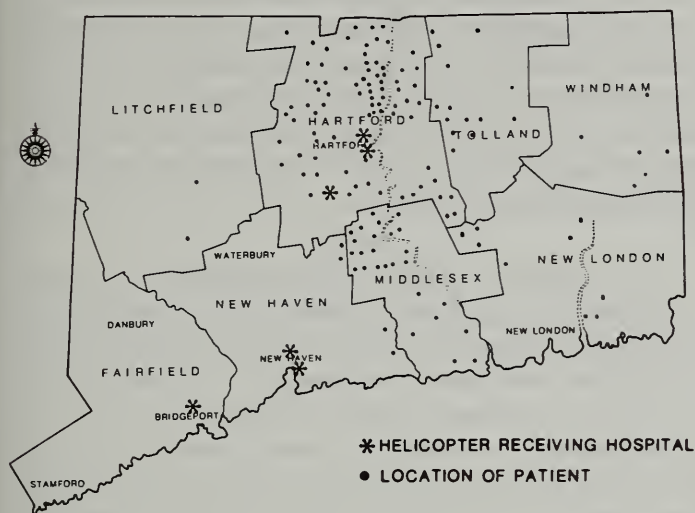
LIFE STAR has responded to accidents in 91 different Connecticut towns, four Massachusetts towns, four New York towns, and two Rhode Island towns. Scene flights are concentrated in Hartford, Tolland, and Middlesex counties. The greatest number of scene flights are in the towns of Glastonbury (28), and Windsor (27), East Windsor (25), and Suffield (25). EMS regions 3 and 4 are the location of most scene flights with a total of 621 (93%). EMS region 3 is eastern Connecticut and EMS region 4 is north central Connecticut. EMS region 2, south central, and region 5 northwestern Connecticut have only generated 44 flights to the scene. LIFE STAR has been requested to an accident scene in EMS region 1, (southwestern Connecticut), only twice and neither request resulted in a completed patient flight. This skewed pattern of completed scene flights clearly indicates that a significant portion of Connecticut is not utilizing the system (Fig 10-12). Distance may explain why the service is not summoned to areas further from the home base. However, it should be noted that LIFE STAR did complete 10 scene flights in New York, western and central Massachusetts, and eastern Rhode Island.

Distance and time factors alone can not account for this pattern. An aeromedical service has a flight crew that is extensively trained in advanced life support procedures. Because of the severity of injuries or illness in the patients that the crew encounters on a regular basis, they have attained a high success rate in the performance of naso- and orotracheal intubation, intravenous access, and dysrhythmia recognition. The aircraft allows these personnel to cover a larger geographic area than could be covered by multiple small numbers of ground ALS personnel. In order to provide the same level of care by personnel in ground ALS vehicles it would necessitate extensive training, multiple vehicles equipped with expensive ALS equipment, and an integrated communication system with local medical directors. Even if this were politically acceptable, the issue of skill decay due to infrequent skill performance would have to be addressed. EMS in regions 1, 2, and 5 should review the protocols

for requesting the service so that critically injured scene patients can be given the benefit of this comprehensive service.

Figure 10

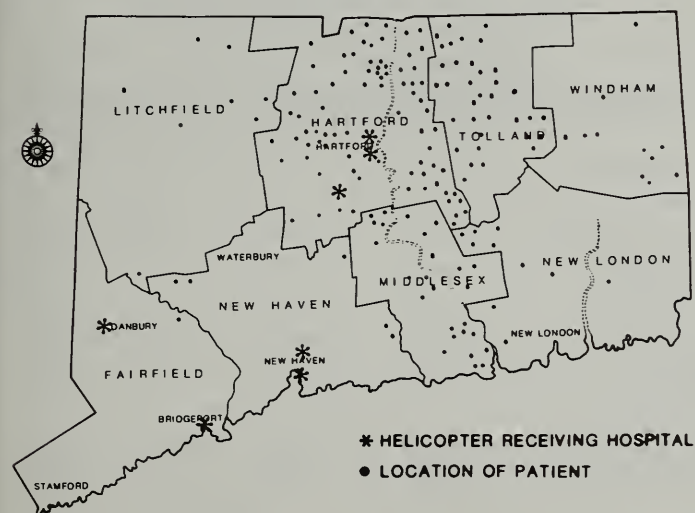
COMPLETED SCENE FLIGHTS ORIGINATING IN CONNECTICUT
BY TOWN: JUNE 1985 - JUNE 1986



Most patients from the scene have been transported to Hartford Hospital or to St. Francis Hospital and Medical Center, since the majority of requests originate in EMS regions 4 and 5. After the Hartford based hospitals, the main receiving hospitals for scene victims are Yale-New Haven and the Hospital of St. Raphael.

Figure 11

COMPLETED SCENE FLIGHTS ORIGINATING IN CONNECTICUT
BY TOWN: JUNE 1986 - JUNE 1987



Interhospital Transfers

Sixty-nine percent of all completed flights involve the transfer of critically ill or injured patients between medical facilities. These patients have been transported to 53 different hospitals in seven states. Patients have been transferred as far as the University of Pennsylvania and Children's Hospital in Philadelphia. Of the 1,524 interhospital patient flights, Hartford Hospital was the receiving hospital for 894 (59%), Yale New Haven for 122 (8%), University of Massachusetts Medical Center for 75 (5%), and St. Francis Hospital and Medical Center for 66 (4%).

The LIFE STAR crew has flown to 106 different hospitals in five states to move critically ill or injured patients to more specialized medical facilities. The transferring hospitals that have utilized the system most frequently are Windham Hospital in Willimantic (n=122, 8%), Charlotte Hungerford Hospital in Torrington (n=113, 7.4%), Middlesex Hospital in Middletown (n=103, 6.8%), and Shoreline Clinic in Essex (n=92, 6%).

Disaster Response

LIFE STAR and its crew responded to four mass casualty/disaster incidents. These events included a building explosion, hotel fire, bus rollover, and a plane crash with the total number of victims being 67. The LIFE STAR crew performed five functions; provided an augmented response, directed triage, provided medical care, evacuated victims, and performed air surveillance. The role of the aeromedical crew has been incorporated into the "Guidelines for Helicopter Operations in a Mass Casualty Response in New England" developed by the New England Council for Emergency Medical Services.¹⁵

Safety

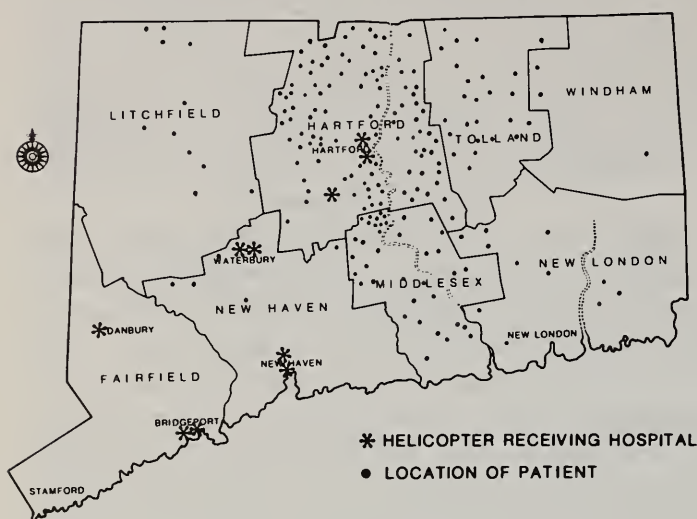
Safety within an EMS helicopter service is of critical importance. No accidents or incidents have occurred during the three and one-half year period of operation of LIFE STAR. The ultimate responsibility for decisions related to the safety of the inflight portion of each specific helicopter flight belongs to the pilot. By protocol the pilot is blinded to the nature of the patient's condition until he has made the decision that the flight can be performed according to all safety guidelines. These guidelines include weather conditions, aircraft loading, and weight and balance. Four pilots and one mechanic employed by Rocky Mountain Helicopters staff the LIFE STAR program. The Federal Aviation Administration (FAA) governs the aviation portion of the program through its regulations. The on duty pilot is stationed in private quarters at the hospital close to the helipad. The standby pilot is on call for relief in the event that the duty pilot feels he is necessary for back-up even though FAA maximum limits have not been reached. The principle responsibility of the pilot is the safe operation of the aircraft. He is not taxed with any additional responsibilities by the hospital nor does he assist with the medical care of the patient. Maintenance of the aircraft as regulated by the FAA and is performed by the onsite full-time mechanic.

The pilot determines the appropriateness of any landing zone. Technical assistance for landing area decisions and planning is offered and given to a number of Connecticut hospitals. A Connecticut state license is not required if total annual landings and takeoffs do not exceed 36. Those hospitals who have both an FAA license and a Connecticut state license are; Bridgeport, Danbury, Hartford, Norwalk, St. Francis, St. Mary's, St. Raphael's, St. Vincent's, Sharon, Waterbury, Windham, and Yale-New Haven.

As part of a LIFE STAR outreach program, over

Figure 12

COMPLETED SCENE FLIGHTS ORIGINATING IN CONNECTICUT
BY TOWN: JUNE 1987 - JUNE 1988



17,700 representatives from safety agencies, community and civic groups, and hospitals have attended presentations by flight crew members. The main focus of this slide presentation is to instruct attendees in the indications for calling LIFE STAR, selection and preparation of landing zones, and safety procedures. An additional 18,000 spectators have attended LIFE STAR demonstrations with the aircraft and the crew. Many mock patient scenarios have been practiced by the crew and EMS responders on scene with a focus on safety procedures.

Ten LIFE STAR safety patch programs have been conducted across the state of Connecticut. The program focuses on safety practices and indications for calling the aircraft. Attendees are required to complete a written examination before receiving a safety patch. The patch, worn on the sleeve of first responders, when seen by the LIFE STAR crew, indicates someone who has attended the program and is familiar with the procedures related to the aircraft.

Age and Gender

Of the total 2,251 patients transported, 1,560 (69.3%) were males and 691 (30.7%) were females. Males accounted for 73.3% of those patients transported from the scene and for 67.7% of the interhospital transfers. This gender differential increases when viewing only trauma patients, with males accounting for 78.2% of all trauma patients transported.

The average age of all patients is 34.7 years. Interhospital patients are somewhat older than scene patients on average, 36.7 years of age v 30.8 years of age. The age/gender composition of LIFE STAR patients described above points out a major fact of injury epidemiology: injury in America is a disease of young males.

Oversight Committee and Medical Audit

Pursuant to Connecticut General Statutes, Chapter 368d, Section 19a-180, Hartford Hospital applied for licensure of its air ambulance service through the state Office of Emergency Medical Services (OEMS). The

Minimum Quality Standards for Emergency Medical Service Helicopter Services requires that "there shall be a medical review committee for the entire Connecticut EMS Helicopter System." This review committee, the Helicopter Oversight Committee (HOC) is chaired by the medical director of OEMS. HOC has designated the following Connecticut hospitals as helicopter destination hospitals; Bridgeport, Danbury, Hartford, New Britain General, St. Francis, St. Mary's, St. Raphael's, St. Vincent's, Waterbury, and Yale New Haven (Fig 10-12). The HOC and the OEMS has established procedures for who may call LIFE STAR, a requesting protocol, and loading and landing procedures.

Audit

The medical care review subcommittee of the HOC has approved the audit method utilized by Hartford Hospital. Four medical audits have been conducted during the first three years of operation. To accomplish the audit, patients within each of the following four groups were reviewed to identify any inappropriate transports: 1) patients having a trauma score (TS) greater than 12 and an injury severity score (ISS) less than 16, 2) patients who die in the emergency department (ED), 3) patients who were discharged within 24 hours, and 4) medical transports (scene not interhospital). All patients identified in these categories were reviewed. Over 80 data elements were evaluated for each patient in a matrix format. Each patient was then critically evaluated by a five member review committee including trauma surgeons, emergency physicians, and flight nurses. Table 1 describes the results of the audits.

Table 1
Summary Audit of Scene Flights - 1985-1988
Total Scene Flights, N = 533
Total Scene Flights Audited, n = 208
Total Audited Flights Justified, n = 182

	1985-86	1986-87	1987-88	TOTAL
Total Scene Flights	161	172	200	533
TS>12, ISS<16	13/14*	23/30	21-26	57/70
Discharged <24 Hours	3/4	5/7	346/8	14/19
Deaths ED	18/18	31/31	34/34	83/83
Medical Scene	8/12	13/15	7/9	28/36
OF TOTAL AUDITED	42/48	72/83	68/77	182/208
% Justified	88%	87%	88%	88%
OF TOTAL SCENE FLIGHTS				
% JUSTIFIED	96%	94%	95%	95%

*Number Justified/Number Audited

Of the 533 scene flights in the first three years of operations, there were only 26 flights identified as not justified (false positive calls). This equals a positive predictive value of the scene audit criteria of 95% (true positive flights divided by all positive flights). A more complete explanation of the audit procedure can be found in the three year report¹⁶ prepared by require-

ment for the state's health department. These audits indicated that of all scene flights only 5% were not justified (false positive). The audits indicated that the criteria for calling the helicopter are being closely followed and that there is no overuse or abuse of the system.¹⁷ A concern is that the calling criteria may be so specific that there are patients who might require aeromedical transport to a trauma center who are not receiving it. Identification of this potentially underserved group of trauma victims will require data from all receiving medical facilities for both air and ground transported patients. This is currently not available in Connecticut.

Mortality and Morbidity Review

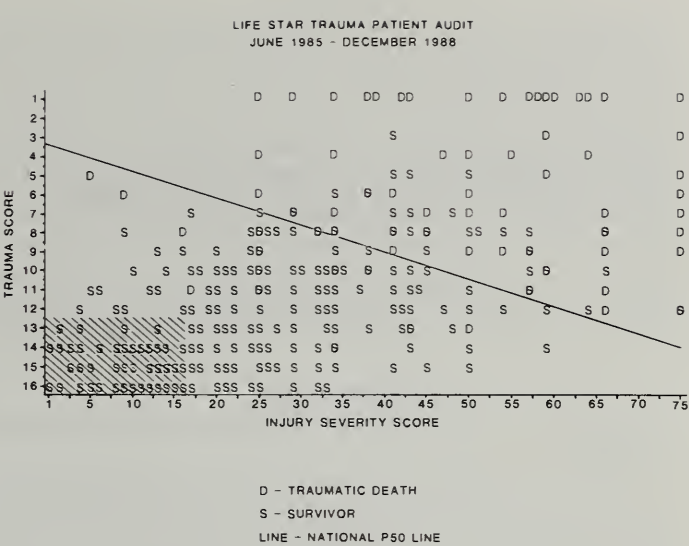
Twice a month, mortality and morbidity reviews are held by the director and/or assistant director of the LIFE STAR program. All deaths and complications are presented, reviewed, and discussed. Protocols, policies, and procedures are clarified during these conferences. These reviews serve as the basis for the nursing audit and the quality assurance which is integrated into the entire system.

Research and Data Analyses

Scientific investigation of various elements of the LIFE STAR program has been used for the purposes of quantifying the effect of the program on patients' lives, identifying aspects of the program that require improvement, comparing outcome with national norms, evaluating new equipment, and evaluating the ability of personnel successfully to perform advanced skills.

Patients can be selected for an audit using the TRISS methodology. TRISS is an acronym for TS,¹⁸ a measure of physiologic compromise, and the ISS,¹⁹ a measure of anatomic derangement. The necessary data elements to complete a TRISS analysis are the patient's TS on scene, the discharge diagnosis in order to compute the ISS, and the patient's age and status at the time of discharge. A graph is then made to determine how actual patient outcomes compare to the expected outcomes (Fig 13). The audit therefore graphically depicts a patient's physiologic and anatomic derangement and compares the patient's actual survival to a calculated predicted survival. The predicted survivals are a result of the major trauma outcome study (MTOS), a national sampling of trauma patients.

The TRISS graph shows trauma patients transported by LIFE STAR. The trauma score and the injury severity score are plotted. The line on the graph denotes a 50% probability of survival. This particular P50 line was determined by the MTOS, a sample of over 80,000 patients from 139 hospitals across the nation. Patients plotted above this line are predicted to die and patients plotted below the line are predicted to live. This graph demonstrates that there are many patients who lived but were predicted to die and a few patients who died but were predicted to live. Patients who are above the line



that live can be audited for evaluation of exemplary care and patients below the line that do not survive are also audited. As a result of the audit it was apparent that one of the problems with the calculation of the ISS is that although the more serious single system injury, eg, a closed head injury, may prove lethal, the patient will have an ISS of only 25. As a result the patient is plotted low on the axis and represents a death below the P50 line. Additionally, the original ISS and TS determinations do not account for some of the complications that develop as a result of the injuries in the older patient who is injured with preexisting medical conditions. Those patients in the left lower quadrangle, those with low injury severity scores and high trauma scores, are all audited as discussed in the previous section.

One study performed showed that the overall survival of LIFE STAR trauma patients (n=779), when compared to the MTOS national norm, is 3 SD better and represents a 4.2% increased survival in the total population above expected. When subgrouped into scene flights and interhospital transfers, patients transported directly from the scene have a statistically significant increase in survival when compared to the interhospital group and national norm. This corresponds to an increase in predicted survival of 7.4% greater than the national norm and 5.8% greater than the interhospital transfers.¹⁶

Another study demonstrated that there is a statistically significant increase in survival between those patients transported to the Hartford Hospital trauma center by air in comparison to those transported to the same trauma center by ground (P=.0004). One hundred seventy-one LIFE STAR patients were compared to 169 historical controls transferred by ground ambulance.²⁰

Other studies and their results can be reviewed in the three year annual report submitted to the OEMS as a requirement of the certificate of need. Subjects included are: outcome of pediatric trauma patients, motion sickness in the crew, hyperventilation in the severely head injured, prehospital triage, intubation, DRG reimbursement, and transport of cardiac patients.¹⁶

Summary

Over 63% of the patients transported by the LIFE STAR crew are the victims of trauma. The system has transported 2,215 ill and/or injured patients, the majority of whom are critical, either from the scene of an injury or from a medical facility to another of greater specialization. With the audit procedure indicating a 95% positive predictive value for summoning this service, LIFE STAR has contributed to the care of critically ill or injured persons in Connecticut and surrounding areas.

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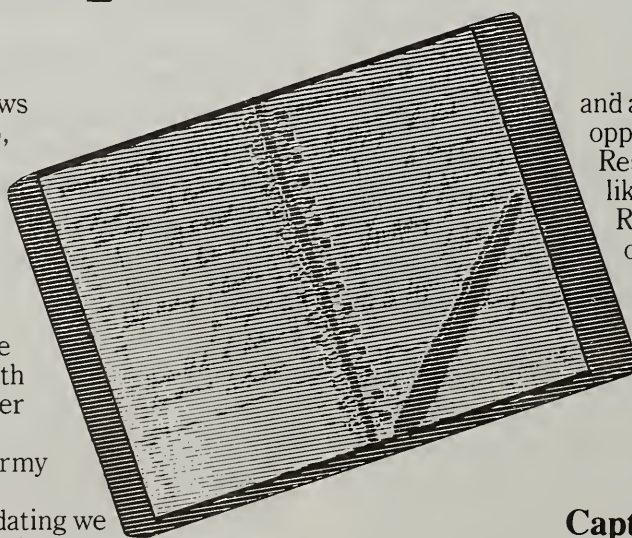
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Low Back Injury in Industry: The Value of a Recovery Program

JOHN McELLIGOTT, M.D., M.P.H., SCOTT J. MISCOVICH, M.D.,
AND L. PETER FIELDING, M.B.

ABSTRACT—Low back pain is the most frequent chronic disabling condition in the United States in patients younger than 45 years,¹ and it is the second largest cause of employee absenteeism.² In this retrospective study involving extreme working conditions at an industrial plant, we found that 20% of all employees incurred a back injury (occupational and nonoccupational) during the 12-month study period, costing more than 5,000 days of work lost, and approximately \$920,000. Based on these findings a three-phased program of education/prevention, physical therapy, and an on-site rehabilitation workshop was implemented. After the first operational year, the net saving to the corporation was \$255,000, and all employees who participated in the program returned to work within 60 days. We conclude that good job design, employee education on back injury prevention, and immediate on-site rehabilitation for injuries incurred can reduce employee disability and lost work time thus benefiting the employer and employee alike.

Introduction

EACH year, 2% of the total United States work force will incur low back injuries, resulting in a loss of 1,400 days of work per thousand workers because of low back pain.³⁻⁵ Except for upper respiratory tract infections, low back pain causes the most lost time from work,² disabling an estimated six to eight million people per year⁶ with a cost to industry of \$14 billion annually in the United States.⁷ Furthermore, 90% of the total costs of these injuries (two-thirds compensation and one-third medical costs) is attributable to only one-quarter of those who are injured. Twenty percent of all patients with low back injuries eventually experience some form of chronic pain syndrome, which accounts for some 80% of the total medical expenses for this condition.⁸⁻¹²

The natural history of low back pain reveals that more

than three-quarters of the patients have sufficient symptomatic improvement to return to work within six to 12 weeks even if no treatment is provided,^{3,13} Bed rest has been the mainstay of therapy with specific treatment schedules varying from none to a few days to two weeks.⁶ Deyo and associates¹⁴ have reported that bed rest for two days is superior to bed rest for seven days because the former results in a more rapid return to work. This approach is effective but not a "cure-all" because therapy must be designed to meet individual needs and bed rest is only one mode of treatment in a comprehensive recovery program.

Thus the prevention of chronic low back pain resulting from an acute injury is important to both individual patients and to the industry. Historically, prevention and rehabilitation programs have shown success in reducing the incidence of low back injuries, loss time from work, and the overall expenditures incurred by injury.^{15,21} However, there are few reports that demonstrate the financial feasibility of a comprehensive prevention and rehabilitation program in the workplace.

Those involved in industrial management have attempted to control the occurrence of low back injuries by the use of employment selection criteria, training procedures, and job design.²² Surprisingly, such employee screening does not reduce the incidence of low back injuries, but, by contrast, good job design resulting from ergonomic study can prevent as many as one-third of low back injuries.⁶

In this study we analyzed the job designs of an industrial plant and made recommendations that could alleviate causes of back injury. With the cooperation of the insurance carrier, we also determined the financial effect that low back pain had on the industry by a retrospective study of 5,000 employees; this is described in the first section of this paper. The results of this study prompted the establishment of a program of prevention and rehabilitation within the industrial plant, which is reported in the second half of this report. The financial data supplied by the insurance carrier were the impetus for a proposal that attracted upper management and was paramount in

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establishing the prevention and rehabilitation program.

Retrospective Study

Methods

A retrospective review of 5,000 employee records from May 1979 through June 1980 was conducted at an industrial plant. The records were obtained using a computer search with the International Classification of Diseases. Back problems relating either to the lumbar or thoracic spine were reviewed, and the patients' records were evaluated for "costs" of time off work that resulted from low back injuries either in the workplace (occupational group) or in the social setting (nonoccupational group).

The data recorded were: lost wages, medical expenses, health insurance costs, and administrative expenses (both direct and indirect). The cost of legal claims and loss of revenue to the employer because of resulting absenteeism were included in the administrative expenses. The cost of lost time was calculated based on eight hours per day at \$9.48 per hour, which was the average hourly rate for these employees during the period of study. An additional 26% of these costs was added to account for the overtime to complete work projects plus the direct and indirect costs that were incurred by the paperwork generated when an employee was absent because of injury.

On-site job evaluation, which included analysis of work site, job design, ergonomics, and interviews with employees was carried out to identify the causes and potential risk factors of back injury in the workplace.

Results

Occupational Group

Our study revealed 280 back injuries, which incurred 1,447 days of lost time from work. These injuries cost a total of \$522,000 made up by insurance medical claims (\$195,000), associated claims for supplemental suits (17 cases, \$188,700), and loss of employee time for 1,447 days (\$138,300). Four employees required permanent restrictions, and one was permanently disabled as a result of an occupational back injury.

Many of the jobs at this workplace required heavy lifting, torqueing, frequent and prolonged bending and stooping, as well as assembly line work requiring mild to moderate repetitive work. Approximately one-half of the injuries occurred while employees were lifting heavy objects or were working on the assembly line. The remaining injuries were distributed among the employees including sedentary office personnel. A review of the mechanical problems or job ergonomics revealed that heavy physical work, frequent bending and twisting, repetitive work, vibration, and static posture were risk factors predisposing to low back injuries. These findings are consistent with other data.²³ The on-site job evaluation revealed some risk factors to low back injury, and changes were made within the workplace to reduce these risks. To reduce extreme torqueing, mechanical assist devices were used to control large valves; assembly line stations were redesigned to reduce excessive bending at

the waist and to eliminate stooping positions; limits for weight lifting were reduced to a maximum of 50 pounds, above which a mandatory two-man lift was required and/or a mechanical assist. Foot stools were custom-made for sedentary personnel so as to increase the pelvic tilt while at desks or work stations.

Nonoccupational Group

In the nonoccupational setting, there were 740 back injuries, which resulted in 3,804 days of work loss and cost a total of \$396,000, made up by insurance medical claims (\$32,400) and loss of employee time (\$363,600). Three nonoccupational injuries required permanent restriction or resulted in partial disability. Jobs were evaluated and work stations were modified to prevent and minimize any occupational aggravation to a back injury.

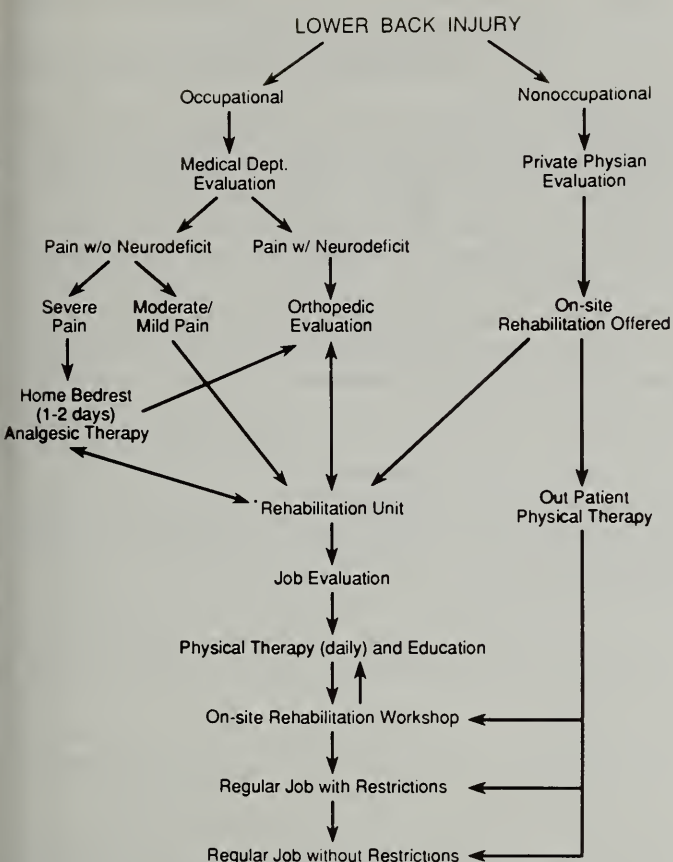
Prevention and Rehabilitation Program

A background of the preprogram negotiations is necessary to appreciate the methods used. Instituting programs of this magnitude are not without problems. Convincing upper management of the benefits of such a program, in this instance, took several years. Initial proposals presented by the plant medical department were met with multiple concerns including conversion of nonoccupational injuries to occupational, start-up costs, and acceptance by the labor union. Positive gains were made only after documenting the overall direct as well as indirect costs of low back injury, which far exceeded the initial start-up expenses. When upper management endorsed the program, we attempted to educate supervisory personnel. Unexpectedly, this proved to be the most frustrating and difficult task. However, once upper level supervisory personnel accepted the goals and objectives of the program, they, in turn educated their peers. The last hurdle was labor, who presented with an unexpected "wait-and-see" attitude; labor became, however, the most vocal supporter of the program after successful rehabilitation of several of its members. The union's initial concerns were that worker classification would be broken and that management would attempt to pay a lower salary scale for less technical work (ie, job restrictions because of back injury could result in a lower pay scale). This indeed was not the case, and, after the initial start-up period, upper management, supervisors, and labor were satisfied, and the plant medical department insured that the patients' welfare was their primary concern.

Employee participation was also a problem since it was voluntary and required the complete agreement of the employee's physician. The "wait and see" attitude prevailed here also, and a successful program was needed to ensure future employee participation.

Methods (See Algorithm)

The first phase of the program was an educational lecture that was given to all employees and included a description of the anatomy of the back, the mechanisms of injury commonly associated with low back injuries, and an extensive section on the prevention of back inju-



Prevention and Rehabilitation Program: Phase I: Plant-Wide Education (Lecture and videotape); Phase II: On-Site Physical Therapy Program for Employees With Low Back Injury; and Phase III: On-Site Rehabilitation Workshop.

ries. A videotape covering these areas was shown to all new employees.

The second phase of the program was the establishment of an on-site physical therapy facility for occupationally and nonoccupationally injured patients. This unit was staffed by therapists who acted in coordination with the company's medical department. Patients were initially evaluated by the company's physician and if they had no neurologic signs, they were referred for the physical therapy. Private physicians were encouraged to tour the facility, and if it was mutually agreeable, their patients had the option to participate in the program. The baseline evaluation was recorded and was immediately followed by ice-pack treatment with range-of-motion exercises. Thereafter, patients received physical therapy to improve range of limb motion, and muscle strength, and flexibility. Treatments were given one to three daily, using diathermy, ultrasound, and whirlpool techniques.

The third phase of the program involved the development of an on-site rehabilitation workshop that provided specialized jobs in a protected environment for patients in the physical therapy program. These jobs included tasks that required minimal physical exertion and that had been previously sent out of the plant for completion but could usually be performed as benchwork. The goals of the workshop were to facilitate recovery, to reduce time off work, and to maintain the work ethic. This

program was unique in that during this phase of the rehabilitation period, the patient restored his feeling of self-worth by being productive once again to his employer.

Results

The program had 273 participants in its first operational year. All patients returned to work within 60 days and no employee required disability payments. The rehabilitation program was a success both to the employees and employer and saved twice the amount of its set-up costs in its first year of operation. The calculated cost saving for the 104 occupationally injured patients was \$138,044, while the saving for the 169 nonoccupationally injured patients was \$225,231. Thus, the total annual saving was \$363,275. The operational costs and the initial program establishment fees were \$108,000, which resulted in a net saving of \$255,275. The program was immediately expanded to include all medical problems that could benefit from the system (eg, recovery from both surgical and medical illnesses).

Apart from the financial savings (which allowed the program to continue) there were other advantages of the system in the psychosocial area: less clinical depression, maintenance of the sense of personal worth, and the desire to work and to contribute to the organization that had made the program available.

Furthermore, the opportunity to return to "light" work made the transition to "normal" employment easier and avoided the "all-or-none" rule insisted upon by many employers. This flexible policy benefited both employee and employer alike.

Discussion

More than 20% of all employees suffered low back injuries during the 12 months of the study. The combined occupational and nonoccupational injuries resulted in more than 5,000 days of time lost from work before the prevention and rehabilitation program was instituted. Furthermore, eight patients had become partially or permanently disabled in the period of the retrospective study. The total costs of both occupational and nonoccupational back injury in the preliminary study was \$920,000.

These data are not new and several studies have been conducted to establish better ways of reducing the financial, physiological, and psychological costs of low back injury.^{3,24-33}

There are many theories about successful rehabilitation for patients with low back injuries. Bergquist-Ullman and Larsson analyzed three different types of treatment in a controlled series at a car manufacturing plant (Volvo).³ Patients who received back-school training returned to work one week earlier than those who received physical therapy that included manipulation or short-wave diathermy. Furthermore, patients receiving back-school training had fewer back injury recurrences during the following year.

Some studies in animals support the notion of early

mobilization after injury. Nachemson studied vertebral disc nutrition in dogs and found benefits from moderate activity defined as exercise of 30 minutes three to four times a day.³⁴⁻³⁶ Other investigators have shown that cartilage, muscle, tendons, and ligament injuries benefit more from immediate activity than from inactivity.^{24,29} Additional analysis of the causes of chronic back pain reveals demineralization of the axial skeleton accompanying enforced rest.³⁰

Another important aspect of chronic back pain is the associated psychosocial problems, which have been well documented.^{37,38} As the disability period increases, there is a decreased chance for rehabilitation to a fully active life.^{10,39} Studies have shown that when back pain becomes persistent, the incidence of low self-esteem, as well as the incidence of chronic drug dependence and alcohol abuse, increases.⁴⁰⁻⁴⁵

It is now apparent that many people are becoming "lost" to the workplace and society and are forced to lead unproductive lives because of the lack of an organized comprehensive back program. This unproductiveness was evident from our retrospective study and from that contained in the literature.³² It is clear that no single measure will effect an improvement in the prevention or management of this condition, however the three-phased program described in this study could provide a much-needed model to change the current outcome of patients with back injury. Companies too small to have in-house medical facilities could be joined through a community hospital in order to form a consortial group to achieve the necessary "critical mass" for success.

This approach is encouraging and long-term studies need to be pursued that examine not only the financial aspects but also the clinical data in a statistically sound manner.

Acknowledgments

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Lumbar Sympathectomy: A Place in Clinical Medicine

ROBERT S. BOLTAX, M.D.

ABSTRACT—Currently lumbar sympathectomies are infrequently performed because the effectiveness of the procedure is unclear. The previous indication of limb-threatening ischemia has been usurped by distal arterial reconstruction. Some vascular surgeons feel there is no remaining clinical role. This paper suggests four categories of patients, represented by five case reports, where lumbar sympathectomy may prove beneficial: 1) Hypertensive patients with painful leg ulcers; 2) Toe and foot amputations in which arterial reconstruction is not feasible; 3) Posttraumatic causalgia (sympathetic dystrophy); 4) As an adjunct to distal graft bypass.

LUMBAR sympathectomy, frequently performed in the decades from 1949 to 1979 for attempted limb salvage in patients considered to have nonreconstructible vascular occlusions and foot ulcers is now even more controversial as a clinical surgical procedure. Following reports by Tyson et al (1969),¹ Kaminski (1972),² Auer (1973),³ and Turnipseed (1977),⁴ bypass to the distal tibial and peroneal arteries is the primary procedure for limbs threatened as the result of advanced vascular disease. The role of lumbar sympathectomy consequently declined and is now rarely used. Some vascular surgeons regard the operation as applicable only in the treatment of causalgia (sympathetic dystrophy). Others are convinced that a wider clinical application is acceptable but are uncertain about indications. This paper will review several patients and outline suggestions for the role of lumbar sympathectomy in clinical practice.

Case Reports

1. JC was a 71-year-old hypertensive nondiabetic black male with a three-month history of a painful ulcer along the lateral aspect of his right lower leg. Ulceration followed minor trauma and did not heal with local care supervised by his family physician. History included a previous cerebral vascular accident with little residual. He smokes several cigarettes a day. Arteriography demonstrated occluded distal popliteal and tibial vessels with

peroneal reconstitution. The patient had significant cardiac disease and, therefore, direct arterial reconstruction was reserved as a last option for limb salvage. Consequently a lumbar sympathectomy was performed and the ulcer was treated with a split thickness skin graft. This healed well and the ulcer is now completely closed.

2. EG was a 67-year-old male with a twenty-year history of scleroderma. Four months prior to admission his right second toe became infected and turned black. The great toe and the fifth toe also ulcerated superficially and the entire leg swelled and became erythematous. The skin of his feet and lower legs was thickened and inflexible. Excellent femoral and popliteal pulses were present but distal pedal pulses could not be found. The feet were sweaty. Arteriography of his right leg demonstrated patent vessels down to the malleoli where the peroneal and anterior tibial arteries ended abruptly. The posterior tibial artery also ended but reconstituted the plantar arch by collaterals. The dorsal arch was not seen at all. Transmetatarsal amputation and lumbar sympathectomy were performed with healing of the foot.

3. LC was a 27-year-old female who was seen three months after an injury to the left foot which probably included a fracture of the tarsal bone, although this was not clear on the initial films. The foot became painful, cyanotic, and cold. The pedal pulses were not palpable. Arteriography using tolazoline hydrochloride suggested marked vasospasm. Seven and one-half months after the injury a lumbar sympathectomy was performed. The foot became warm and pink and no longer tender. She was able to resume walking with the use of a cane. There is x-ray evidence of ankle joint posttraumatic arthritis.

4. EK was a 67-year-old female who had pain and numbness in the left foot for several months followed by toe ulcerations and drainage. Femoral and popliteal pulses were palpable but there were no pedal pulses. Arteriography revealed patent vessels to the midcalf where there were occlusions of the anterior tibial and peroneal arteries. There was also occlusion of the posterior tibial artery with distal reconstruction of a short segment extending into the foot. It was felt to be a "blind" segment. An *in situ* saphenous vein femoral-to-

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distal posterior tibial artery bypass graft was created along with a lumbar sympathectomy. The graft has remained patent for over two years.

5. HB was a 66-year-old diabetic male with subpopliteal artery occlusion and extensive collaterals which reconstituted the distal posterior tibial artery. There was an infected right great toe. The patient had been insulin-dependent for many years. An *in situ* saphenous vein femoral-to-distal-posterior-tibial bypass graft and lumbar sympathectomy was performed. The graft remained patent for seven months and then thrombosed. Attempts at revascularization were unsuccessful and a belowknee amputation was required.

Discussion

Hypertensive skin ulcers usually occur on the lateral aspects of the lower legs. The ulcerations are painful and resistant to healing even with conscientious local care. This is in contrast to venous ulcerations which are usually medially located, have minimal pain, and respond well to elevation and local care. Minor local trauma causes the initial break down in both instances.

Patent large vessels in the leg assure good muscle and distal blood flow but do not insure arteriolar and capillary flow to the skin. Some hypertensive patients have a considerable element of small vessel vasospasm. Lumbar sympathectomy and local ulcer treatment including split-thickness skin grafting may be required to improve the microcirculation and permit subsequent healing. Fortunately, improved medical management of hypertension over the last decade has resulted in a declining incidence of hypertensive legs ulcers.

Scleroderma involves the thickening of the connective tissue components of arterial walls and progressive loss of lumen. This may be severe enough to lead to low flow and resultant spontaneous thrombosis. Early in the process Raynaud's phenomena may play a role causing the skin color changes of diminished circulation and eventual skin break down. Scleroderma typically involves the skin of the toes, feet, legs, fingers, hands, and arms. In severe cases the entire surface of the body may be affected including mucous membranes.

The role of sympathectomy for scleroderma patients remains controversial. Cervicodorsal sympathectomy for finger ulceration over long-term follow-up has proved to be unsuccessful. The successful use of lumbar sympathectomy for toe salvage has been completely undocumented. In our case the patient required a forefoot amputation because of the extent of ulceration and infection. Sympathectomy was performed in addition because the feet were able to sweat, which indicated persistent sympathetic function and, therefore, an element of residual vasospasm. Studies by Lee indicated increased skin and muscle blood flow and resultant healing facilitated by lumbar sympathectomy.⁵

Causalgia (sympathetic dystrophy) is a clinical syndrome which may be encountered in the lower extremity after trauma. Occasionally the trauma is surprisingly minor—a broken toe or perhaps a severe bruise. The signs and symptoms may include pain, coldness of the foot, cyanosis, sweating, and mottling. As time passes muscle atrophy and bone demineralization is seen. Sympathetic innervation to the leg is through the sciatic nerve which carries a large sympathetic outflow tract. The longer the symptoms persist after injury the less likely it is that the patient will benefit from treatment. In 1987 Mockus reported a series of 84 patients with excellent results from sympathectomy and a total of 94 patients with improvement from sympathectomy.⁶

Finally, is there a role for lumbar sympathectomy when a very distal arterial bypass graft is being done for limb salvage? There do not appear to be any controlled series in the literature concerned with this issue. "Limb salvage" is a last-ditch effort to preserve the limb and, failure generally means either a below-knee or above-knee amputation. Under these circumstances the surgical adage, "when you think of it, do it!" appears to apply. So does the "art" of surgery. Why some bypass grafts in limb salvage circumstances remain patent and others close, as presented in the contrasting last two cases, is unknown. The degree of vascular resistance or capacitance for increased blood flow may play a role; possibly sympathectomy can be helpful under these circumstances.

Conclusion

The role of lumbar sympathectomy remains unclear. There are some applications presented here that may become widely accepted. The "hypertensive ulcer" usually responds and sympathectomy may be a way to avoid a significant arterial reconstruction in a risky medical patient. Scleroderma with impending "minor" amputation may benefit from sympathectomy with improved wound healing. Causalgia responds well to lumbar sympathectomy especially if performed early in the clinical course. The patient with very distal arterial bypass for limb salvage may benefit from the addition of a lumbar sympathectomy. This procedure may possibly tip the balance in favor of saving a limb.

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Important Advances in Clinical Medicine

Neurology

The Scientific Board of the California Medical Association presents the following inventory of items of progress in neurology. Each item, in the judgment of a panel of knowledgeable physicians, has recently become reasonably firmly established, both as to scientific fact and important clinical significance. The items are presented in simple epitome and an authoritative reference, both to the item itself and to the subject as a whole, is generally given for those who may be unfamiliar with a particular item. The purpose is to assist busy practitioners, students, research workers, or scholars to stay abreast of these items of progress in neurology that have recently achieved a substantial degree of authoritative acceptance, whether in their own field of special interest or another.

The items of progress listed below were selected by the Advisory Panel to the Section on Neurology of the California Medical Association and the summaries were prepared under its direction.

Botulinum Toxin Therapy for Torticollis

BOTULINUM toxin has been used for some years to treat ophthalmologic conditions such as strabismus and blepharospasm in which there is inappropriate or unbalanced muscle activity. The toxin binds rapidly and with high affinity to nerve terminals, so that small amounts injected locally into overactive muscles produce focal weakness without causing any serious systemic side effects.

Recent studies have focused on the role of botulinum toxin in the treatment of spasmodic torticollis and other dystonic disorders. In torticollis, which is usually idiopathic and attributed to basal ganglia dysfunction, there is an abnormal posture of the head due to the overactivity of certain neck muscles. Most of the drugs that have been used in its treatment are of limited usefulness, producing either little or no benefit or mild benefit at the expense of side effects that are often distressing. Accordingly, there have now been several trials of using botulinum toxin to treat torticollis. In general, these studies have shown that compared with placebo, botulinum toxin administered to overactive cervical muscles can produce subjective improvement in between 50% and 80% of patients. The benefit may involve both a reduction in abnormal movements or postures and a reduction in pain. Objective benefit may also occur but is more difficult to show, probably because of the insensitivity of

the objective rating scales that are available. The benefit may last for several months but eventually wanes unless the muscles are reinjected with the toxin.

Overactive muscles can be injected either in the motor end-plate region or at sites distributed throughout the length of the muscle, with similar results. Various doses have been used in the different published studies but usually are less than a total of 300 units at any one time or 180 units to any single muscle. The estimated median lethal dose for humans is 2,500 to 5,000 units.

Side effects are typically minor and short-lived and include local pain or discomfort about the site of injection, neck weakness, malaise, and occasionally dysphagia (which may last for a few days). The cause of the dysphagia is not clear but may relate to a local spread of the toxin to the muscles of deglutition. There is neurophysiologic evidence that local injections of botulinum toxin produce subtle effects on neuromuscular transmission at distant sites, but these effects are not detectable clinically with the usual doses administered for torticollis.

In some patients, botulinum toxin injections are only briefly effective despite a persistent relaxation of previously overactive muscles, suggesting that the pattern of muscle activity in torticollis may change following surgical procedures such as rhizotomy, peripheral nerve section, or muscle section. Botulinum toxin therapy for torticollis is now being used at several major medical centers, but the toxin is not yet approved by the Food and Drug Administration for general use.

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Treating Febrile Seizures

FEBRILE seizures, which occur in about 3% of children between the ages of 3 months and 5 years, often recur (30% to 40%) but are rarely associated with long-term neurologic sequelae or the development of epilepsy or nonfebrile seizures (7% by age 25). The development of nonfebrile seizures later in life occurs more frequently in infants whose febrile seizures are "complex"—that is, focal, prolonged over 30 minutes, or repeated seizures with the same illness—and particularly if these complex features appear in an infant who is already known or thought to have neurological abnormalities. The risk of nonfebrile seizures appearing up to the age of 25 years ranges from 2.4% among children with simple febrile seizures to 49% in the small number having all three complex features.

In a discussion of the treatment of febrile seizures, attention must first be directed to the acute event. Most (95%) febrile seizures are short-lived (less than 30 minutes); 81% are nonrecurrent during a particular febrile illness. Anticonvulsant therapy is indicated if the seizures have not stopped before the infant reaches a physician's office or emergency department. Parenteral lorazepam, 0.05 to 0.1 mg per kg body weight, is the antiepileptic drug now preferred by many pediatric neurologists, though the use of parenteral phenobarbital, 10 mg per kg, is still popular. If the seizure is short, then refraining from treating with antiepileptic drugs is acceptable therapy. The infant should then be evaluated for the source of the fever, and the appropriate antipyretic therapy started. The place of routine lumbar puncture in evaluating febrile seizures is debated, but most physicians agree that infants with focal or unilateral seizures, suspicious findings on the physical examination, such as rash or petechiae, hypotension, or grunting respirations, or on a neurologic examination, such as neck stiffness, abnormal tone, an altered level of consciousness, eye deviation, or abnormal fontanel tension, should be tapped. If it is likely that the parents will not comply with follow-up in the next few days, then a lumbar puncture should be considered.

The issue of long-term therapy must be considered in light of the fact that the prophylactic use of antiepileptic drugs, either short- or long-term, will reduce the inci-

dence of recurrent seizures but have no effect on the risk of the later development of nonfebrile seizures. There is also no compelling evidence that febrile seizures per se cause neurologic injury, though some clinicians think that severe or recurrent febrile seizures occur more frequently in children in whom temporal lobe epilepsy ultimately develops. Some physicians advocate instituting the prophylactic use of antiepileptic drugs in so-called high-risk infants, that is, those younger than 12 months, or who have had a previous complex febrile seizure, and those infants with developmental delay, evidence of a neurologic impairment before the seizure, or with temporary neurologic abnormalities after a seizure (Todd's paralysis). None of these factors, however, except for the age at the initial seizure, are major predictors of recurrence. For example, most complex seizures occur as the first seizure and are not predictive of subsequent seizures. These facts certainly support a nontreatment approach to all children with febrile seizures.

Continuous prophylactic therapy has traditionally been accomplished with phenobarbital, though using valproic acid and primidone has also been effective. All of these drugs have substantial and on rare occasions lethal side effects, which has led to the use of intermittent prophylaxis with rectal diazepam. The parenteral solution can be instilled in the rectum at a dose of 0.5 mg per kg (maximum dose 10 mg) at the first sign of a fever or when a seizure occurs. The former approach has been shown by many investigators in Europe and in yet-unpublished studies in this country to reduce the risk of recurring febrile seizures. Administering the drug when the seizure begins, which is now being done with severely epileptic children, reduces the duration of the recurrent seizure and obviates a trip to an emergency department. Side effects are few. The rectal use of lorazepam has also been effective in aborting status epilepticus in epileptic infants and children and will probably become the drug treatment of choice in the intermittent prophylaxis of febrile seizures.

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Optimal Drug Management of Parkinson's Disease

FOR several years a combination product of carbidopa and levodopa (Sinemet) has been the principal drug in the treatment of Parkinson's disease. We favor beginning a careful titration of the drug within the first

year or two of clearly defined symptoms, at the point when a patient begins to be disabled. This strategem is based on evidence showing that early treatment results in a longer lifespan and that late complications have been related to the progression of the disease and not to the duration of dopa treatment. An opposing claim is that dopa has a finite usefulness and treatment is better postponed until later in the course of the disease.

Sinemet 25-100 (containing 25 mg of carbidopa and 100 mg of levodopa) is typically administered with half a tablet two or three times a day with food, gradually increasing over the next few months to three or four whole tablets a day. If adequate benefits are not achieved by then, switching to Sinemet 25-250 (carbidopa, 25 mg, and levodopa, 250 mg) may be helpful, using half tablets initially and whole tablets subsequently. Each stepwise increase should be given only after a careful evaluation of rigidity, akinesia, tremor, activities of daily living, and possible side effects, particularly dyskinesia and confusion. Patients should be seen every three to four months.

As the duration of disease increases, the efficacy of each dosage may gradually decrease from four or five hours to one or two hours. This "wearing off" can be treated by administering small doses of carbidopa-levodopa at three-, two-, or one-hour intervals during the day and one or more doses at night. The total daily dose should remain constant.

After some years, choreoathetoid dyskinesia may alternate with the wearing-off effect, resulting in a state that fluctuates between reasonably good control, involuntary movements from too much dopa, and parkinsonian akinesia and tremor. This, too, may be treated by shortening the interval between doses or by adding the dopamine agonist, bromocriptine mesylate (Parlodel). The dosage of bromocriptine, 2.5 mg, is begun with a half or a quarter tablet once or twice a day, gradually increasing to 15 to 25 mg a day over several months.

Another approach is to begin therapy in a previously untreated patient with bromocriptine or pergolide mesylate, a new dopamine agonist soon to be available. Eventually, carbidopa-levodopa needs to be added to this regimen, but some neurologists feel that some of the late side effects of dopa may be lessened or postponed by giving dopa-agonist therapy first. A variation on this is to begin therapy with levodopa combined with a dopamine agonist. Rinne, using a mean daily dose of dopa (combined with a dopa-decarboxylase inhibitor) of about 500 mg, plus a mean dose of bromocriptine, 22 mg, found less end-of-dose disturbance and peak-dose dyskinesia at the end of five years than with the use of levodopa alone. It is critical not to begin giving both drugs at the same time. To separate the immediate beneficial and the side effects of the two drugs, we recommend starting with one drug, gradually increasing to the desired dosage, and then doing the same with the second drug.

Other drugs acting synergistically with dopa include

anticholinergics such as trihexyphenidyl hydrochloride and benztropine mesylate. Amantadine hydrochloride may have both short- and long-term benefits, particularly for tremor.

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Electrodiagnosis of Neuromuscular Disorders

ELECTRODIAGNOSTIC techniques can be of help in the diagnosis, management, and prognosis of neuromuscular syndromes. Motor nerve conduction is determined by recording the compound muscle action potential, usually from a small intrinsic hand or foot muscle, while the nerve is stimulated at two locations. The distal latency reading is subtracted from the proximal latency reading and the difference divided into the distance measurement. Abnormal latencies and waveforms may indicate axonal loss or the presence of nerve conduction block resulting from demyelination and assist in locating the site of such abnormalities.

The F wave, resulting from electrical stimulation of the motor nerve, is an example of a "late response." It occurs when an antidromically conducted action potential reaches the motoneuron and is fired back out to the periphery. Prolonged latencies of late responses when nerve conduction is normal indicate the presence of proximal neuropathy, usually demyelination (acute Guillain-Barré syndrome). The F wave is conducted over the ventral root and is not a reflex. In some muscles, such as the soleus or flexor carpi radialis, it is possible to record the H reflex, which results from the activation of muscle spindle afferents. The H reflex uses the spinal monosynaptic reflex requiring the dorsal root. Disorders selectively involving the dorsal root can be detected by comparing the F-wave and H-reflex responses.

Sensory nerve action potentials are recorded from the skin or by near-nerve needle recording. Cerebral and spinal evoked potentials can also be recorded after nerve stimulation. These potentials often require signal averaging to record. The technique permits an investigation of disorders of the sensory nerve affecting large myelinated fibers and connections to cerebral cortex.

A repetitive stimulation of motor nerves while recording the compound muscle action potential (CMAP) is used to evaluate neuromuscular transmission. A decline in the amplitude of the CMAP at slow rates of stimulation indicates a postsynaptic defect; the reduced amount of acetylcholine produced following each nerve impulse finally falls below the level sufficient to activate some muscle fibers. A presynaptic defect, as seen in botulism or the Lambert-Eaton Syndrome, causes an increase in amplitude with high rates of stimulation (> 10 Hz) as the release of acetylcholine is facilitated by increased levels of extracellular calcium associated with repetitive stimulation. The amplitude of the CMAP from a condition of rest is below normal.

A quantitative analysis of the amplitude, duration, and waveform of the motor unit action potential recorded by a needle electrode can be used to detect signs of motor unit loss, denervation, reinnervation—early and late—and muscle fiber loss. This technique can characterize the extent and severity of neurogenic atrophy as well as of myopathy.

The single-fiber electrode records the potentials of single muscle fibers from within a small electrode recording area. Two or more muscle fiber potentials can be recorded from within the same motor unit. By triggering the sweep of an oscilloscope with the single-fiber potential and delaying the display of action potentials, the synchrony of the firing of fibers and their density within the motor unit can be determined. Such studies are helpful in diagnosing disorders of the neuromuscular junction when the results of other studies are normal.

The latency and amplitude of reflexes can be used to assess central connections important for the reflex and the integrity of each limb. For example, the blink reflex can be used to evaluate an oligosynaptic ipsilateral response of orbicularis oculi muscle in response to stimulation of the trigeminal nerve, as well as a polysynaptic, bilaterally represented later response with pathways in the pons and medulla. Combined with motor conduction studies of the seventh nerve, lesions within the pons can be differentiated from those affecting one limb of the reflex.

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Nervous System Effects of Toluene and Other Organic Solvents

ORGANIC solvents are industrial compounds that produce neurologic syndromes related to both acute and chronic intoxication. Because hundreds of new

organic compounds are introduced each year, many previously unsuspected toxic effects have been recognized. Solvents are highly lipophilic, which explains their distribution to organs rich in lipids, such as the brain. Although extremely high concentrations of all volatile organic solvents produce nonspecific effects, such as encephalopathy, many of these solvents produce relatively specific neurologic syndromes with lower level, longer term exposure. Long-term or persistent specific effects on the nervous system vary with the duration of exposure and whether the central nervous system (CNS) or the peripheral nervous system is primarily affected.

Long-term exposure to the aliphatic hydrocarbons, such as *n*-hexane and methyl butyl ketone, is typically associated with the development of peripheral neuropathy. Animal models developed using these compounds are classic examples of target-organ toxicity affecting the peripheral nervous system. The aromatic hydrocarbons, such as toluene, have been known to cause both acute and chronic CNS toxicity in humans for more than two decades, but because of the lack of an animal model of neurotoxicity and the small number of human cases, understanding the pathogenesis of the CNS effects of toluene has only come recently.

Toluene is the most widely used of the organic solvents and is a major component in many paints, lacquers, glues and adhesives, inks, and cleaning liquids. As with other solvents, inhalation is the major route of entry, though some absorption occurs percutaneously. Of all the solvents, toluene seems to have the highest potential for abuse, and recent studies of habitual inhalant abusers of toluene-containing products have begun to shed light on its chronic CNS effects.

Acute intoxication with toluene produces euphoria, giddiness, and a cerebellar ataxia. Higher levels of exposure will lead to progressively greater degrees of a non-specific encephalopathy. With long-term abuse (usually ten years or more of daily use), neurologic impairment will develop in almost two thirds of abusers. Neurologic abnormalities vary from mild cognitive impairment to severe dementia, typically associated with other neurologic signs such as cerebellar ataxia, corticospinal tract dysfunction, oculomotor abnormalities, tremor, deafness, and hyposmia. Cognitive dysfunction is the most disabling and frequent feature of chronic toluene toxicity and may be the earliest sign of permanent CNS injury. A recent magnetic resonance imaging and neuropathologic study of long-term toluene abusers has shown evidence of diffuse CNS white matter changes, suggesting that the primary effect of toluene may be on CNS myelin or myelin-producing cells.

While it is now clear that habitual toluene abuse leads to permanent multifocal CNS injury from effects on white matter, it is less obvious what happens in industry, where workers have exposure to much lower, presumably "safe," levels of toluene and other solvents. Exposure to solvents in the workplace is a particularly common

situation. Unlike exposure in cases of abuse, where dramatic clinical neurotoxicity is seen following high-level acute and chronic exposures, studies over the past two decades, primarily from Scandinavia, report a syndrome that develops after low-level chronic exposure. This syndrome has been called the "psycho-organic syndrome" primarily because of the nonspecific nature of the signs and symptoms. The most common symptoms of the syndrome are poor memory, headache, fatigue, concentration difficulties, and personality changes (irritability, depression, emotional lability). The results of the neurologic examination in these persons, as well as neuroimaging and neurophysiologic studies, are normal. Only extensive neuropsychological testing has suggested cognitive dysfunction. Although these initial studies were uncontrolled, nonrandomized, and unblind, the psycho-organic syndrome was widely accepted as a clinical illness and soon became a major problem for industry, the legal profession, and physicians. Recent studies, however, have cast doubt as to whether or not the syndrome exists. Several recent, well-designed studies, including one by the Danish group that first reported this condition, have shown neuropsychological differences between workers with or without exposure to solvents.

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Peripheral Neuropathy Associated With Human Immunodeficiency Virus Infection

PERIPHERAL neuropathies occur in a third or more of patients with human immunodeficiency virus (HIV) infection, with the most common type being distal axonal polyneuropathy in patients with the acquired immunodeficiency syndrome (AIDS). Three other types of peripheral neuropathy are also widely recognized: inflammatory demyelinating polyneuropathy, mononeuropathy multiplex, and progressive lumbosacral polyradiculopathy.

In patients with distal axonal polyneuropathy, sensory symptoms typically develop in the feet as the initial complaint. While a third of patients with AIDS have mild distal numbness or paresthesias, 10% of patients with constitutional symptoms from HIV infection—more often AIDS than AIDS-related complex—present for a neurologic evaluation of painful feet. Depressed or

absent tendon reflexes only at the ankle and a decreased perception of sensation in the feet are the predominant abnormalities detected on examination. Although rarely a complaint, mild distal weakness may be present. Nerve conduction studies show decreased amplitude of sensory nerve action potentials as the predominant abnormality, but mild slowing of sensory and motor conduction velocity may also be found. Although patients treated with azidothymidine and other patients without treatment have rarely improved, the condition of most patients continues to worsen despite treatment with azidothymidine, prednisone, or plasmapheresis. Treatment is symptomatic, with the use of tricyclic, antidepressants often reducing the severity of pain. The pathogenesis of this neuropathy is unknown, with possible causes including nutritional deficiency, drug toxicity, and infection.

Patients with inflammatory demyelinating polyneuropathy have weakness either acutely—with the clinical features of the Guillain-Barré syndrome—or chronically. In addition to weakness that includes proximal muscles, tendon reflexes are absent. Sensory symptoms and signs are minor. Electrodiagnostic studies provide evidence for an acquired demyelinating polyneuropathy, with severely reduced conduction velocities, multifocal conduction block, or both. Either of these polyneuropathies may be the initial symptom of a patient with undiagnosed HIV infection, so cerebrospinal fluid (CSF) pleocytosis in a patient with inflammatory demyelinating polyneuropathy suggests the need to determine the HIV antibody status. Nerve biopsy specimens reveal segmental demyelination and mononuclear cell infiltration, and an autoimmune pathogenesis is generally accepted. These polyneuropathies usually respond well to treatment with plasmapheresis, either alone in the acute form or possibly together with the use of prednisone in the chronic form.

Patients with mononeuropathy multiplex and HIV infection typically present with multifocal sensory loss that is more prominent than weakness. Cranial nerves, particularly the trigeminal and facial, may be involved. Patients with this neuropathy typically have constitutional symptoms and other features of AIDS-related complex. Electrodiagnostic studies usually provide evidence for axonal degeneration that varies in severity in different nerve distributions. Nerve biopsy specimens contain perivascular and endoneurial inflammatory cell infiltrates and confirm axonal degeneration; an autoimmune pathogenesis is generally accepted. The neuropathy spontaneously remits in half of patients. Some with progression respond to plasmapheresis or prednisone therapy, with or without the additional features of a chronic inflammatory demyelinating polyneuropathy developing. The remaining patients with progression go on to have more confluent distal symptoms and signs typical of distal axonal polyneuropathy and do not respond to immunotherapies.

Progressive lumbosacral polyradiculopathy occurs predominantly in patients with AIDS. Progressive weak-

ness, numbness, and pain of the legs develop subacutely along with impaired sphincter control. A CSF examination is the most important diagnostic test. In polyradiculopathy due to cytomegalovirus (CMV) infection, the CSF typically has a polymorphonuclear pleocytosis (0.5×10^6 per liter or greater), a low glucose level, and an elevated protein content. Ascending paralysis typically leads to death within two months, but early treatment of CMV polyradiculopathy with ganciclovir has been effective in at least some cases. In one patient with a positive CSF VDRL, antibiotic therapy was curative for a syphilitic polyradiculopathy. Other patients have presented with similar neurologic symptoms and signs but with a CSF that had fewer cells and from which CMV could not be cultured. Some of these patients have had lymphomatous cells on CSF cytologic examination, and these patients have died. Others with normal cytologic findings have shown either continued progression or spontaneous remission; the cause in these cases is unknown.

Thus, peripheral neuropathies are common in association with HIV infection, and each type suggests a particular diagnostic and treatment strategy.

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Diagnosing Heavy Metal Intoxication in Patients With Neurologic Signs

NERVOUS system signs are common in acute and chronic cases of heavy metal poisoning. These include peripheral neuropathy from lead, arsenic, organic and inorganic mercury, and thallium; mental retardation or dementia from organic and inorganic mercury and lead; psychosis from arsenic and inorganic mercury; encephalopathy with seizures from lead and arsenic; and visual disturbances or ataxia from organic mercury.

Most toxicology laboratories use atomic absorption spectroscopy to analyze specimens for heavy metals. This method can detect common heavy metals, is accurate and quantitative, and can be done on blood, urine, hair, or other tissues. The toxicology laboratory should be informed which heavy metals are suspected because the instrument must be adjusted for each element ana-

lyzed. The choice of specimens to submit depends on how recent the exposure was and the duration of the intoxication. In general, blood is the most useful specimen in acute intoxications (within three days), except for arsenic (where, because of arsenic's short half-life, urine is also helpful). For chronic intoxications (weeks to months), urine or hair provides the most useful information.

Care should be taken in collecting specimens to avoid environmental contamination. Whole blood is preferred over serum for heavy metal analysis because metals often accumulate within erythrocytes. The blood specimen should be collected in a heparinized, trace metal-free glass tube. A 24-hour urine specimen should be collected in an acid-washed container (the inside of a plastic or glass container is washed with a solution of 0.1 molar hydrochloric acid, rinsed with distilled water, and then dried). Hair can be used to detect chronic metal intoxications from arsenic and mercury. For the specimen, 50 to 100 strands of scalp hair are cut close to the scalp. The strands are oriented so that the bases of the hairs are together. The bundle of hair should then be cut into thirds and each group of hair strands separately placed into trace metal-free glass tubes that are labeled proximal, middle, or distal scalp hair. A metal measurement of all three specimens will provide an estimation of the duration of the exposure because hair grows about 1 cm per month. Differences in metal content in the three hair sections also decrease the likelihood that the metal accumulation occurred from external environmental contamination, such as from hair washing.

In interpreting heavy metal analyses, it is important to know the normal values from a particular toxicology laboratory. In general, levels that are consistent with significant heavy metal intoxication are at least twofold to threefold above the normal levels for a laboratory. If borderline levels of lead or another heavy metal occur in a patient thought to have chronic intoxication, a diagnostic challenge with calcium disodium ethylenediaminetetraacetate (EDTA) may be considered. In this situation, a baseline 24-hour urine specimen is collected. A second 24-hour urine collection is started and the adult patient is given EDTA, 1 gram in 250 ml of 5% glucose solution given intravenously over one hour. The EDTA dose is repeated 12 hours later. A pronounced increase in the heavy metal content in the second urine collection, usually threefold to fivefold over the baseline specimen, implies substantial exposure to the heavy metal with increased body burden.

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New Strategies in Stroke Treatment

THE incidence of stroke has decreased significantly in recent decades, due largely to a better management of risk factors such as hypertension. This improvement has not been matched by the results of treating acute stroke, which has been directed at restoring or amplifying altered perfusion and preventing the aggregation of formed elements of blood. Using aspirin reduces the incidence of stroke after a transient ischemic attack, ticlopidine hydrochloride use is under study, and other antiplatelet drugs have not been shown to be effective. Heparin and sodium warfarin administration reduces the incidence of cardiogenic emboli but is not beneficial in other types of stroke. The use of anticoagulants in progressing stroke, while customary, has unproven benefits. Thrombolytic agents carry a significant risk of hemorrhage. Dextran sulfate, hemodilution, and pentoxifylline are ineffective.

Our understanding of the pathophysiology of acute cerebral ischemia has attained new levels in recent years. Attention was focused initially on energy substrate availability for ischemic neurons, but high intracellular glucose may increase intracellular acidosis. Other potentially cytotoxic events include alterations of the homeostasis of intracellular ions (especially calcium), an imbalance between prostacyclin and thromboxane production, a net increase in free radical species, and changes in the blood-brain barrier with the formation of edema and subsequent further impairment of the diffusion of oxygen and glucose into the neuron. Each of these has led to the development of a new therapeutic strategy, the results of which are summarized.

The most exciting development in the treatment of cerebral ischemia is recognizing that excitatory and other neuropeptides are released after ischemia and may potentiate cellular damage by augmenting calcium flux into neurons, resulting in their untimely demise.

The mechanisms of the neurotoxicity of calcium influx in ischemia, recently reviewed, are complex. Although calcium channel blockers also affect the vascular tone, recent work indicates that their effect on the calcium homeostasis of the neuron may play a more central role in ischemic damage than previously appreciated. Studies in animals, using centrally acting calcium channel blocking agents such as nimodipine and lidoflazine, have persuasively shown a consistent and substantial beneficial effect on ischemic brain. Furthermore, a single-blind study of the effect of nimodipine use on the clinical course of patients with acute ischemic stroke showed significant functional improvement in the treated group. An additional double-blind study has also shown the use of nimodipine to significantly reduce morbidity and mortality. Currently, multicenter double-blind trials are being carried out to further study the effects of these calcium channel blocking agents in acute cerebral ischemia.

Yet another means of approaching calcium neuro-

toxicity involves the neurotransmitter mediation of neuronal calcium channels. Glutamate is a known excitatory transmitter found in large concentrations in human cortex and hippocampus. Studies completed in the past 15 years have shown that glutamate is a powerful neurotoxin and that its blockage or antagonism greatly diminishes the sensitivity of central neurons to ischemia. The *N*-methyl-D-aspartate (NMDA) subclass of glutamate receptors has the unique characteristics of being linked to calcium-permeable channels. Studies in animals using both a nonspecific excitatory amino acid-receptor antagonists have shown a decrease in stroke size, deficits, and the percentage of severely ischemic neurons. As yet, there is nothing approved for clinical use.

While experimental data have convincingly shown that administering glucose before cerebral ischemia in animals seriously worsens the postischemic outcome, the interpretation of clinical studies in humans is open to debate. One problem is that the critical variable—intracellular glucose—cannot be measured. Nevertheless, it would seem prudent to minimize administering glucose until more definitive data are available.

Several studies indicate that the main cause of early death in patients with stroke is swelling of the ischemic hemisphere and the resulting transtentorial herniation. The results of clinical trials that have investigated the effect of glycerol or dextran use in acute stroke have been inconsistent. Some studies have shown benefits, some have not.

Additional approaches to metabolic treatment involve prostaglandin biosynthesis. There are several metabolic intermediaries in the synthetic pathway that are potentially harmful to intact neurons. These include active oxygen species (free radicals), thromboxane, and leukotrienes. During incomplete ischemia it is postulated that the normal biosynthetic pathway is altered such that the resultant load of these compounds, normally buffered by the cell, becomes toxic. Studies are being done to assay the effectiveness of drugs thought to scavenge the free radicals and to inhibit the production of thromboxane and leukotrienes. Controversy and conflicting claims surround the results of these studies.

These new strategies, especially those dealing with calcium homeostasis, hold great promise for the management of acute stroke, suggesting that previous therapeutic strategies aimed at treating the circulation may be missing the target: the tissue.

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Vitamin E Use in Neurology

VITAMIN E deficiency was for many years thought not to occur in humans. Several deficiency states have recently been recognized, however, and some diseases once thought to be untreatable have now been found to be treatable by supplementing vitamin E.

Vitamin E is a fat-soluble substance abundantly present in a normal diet. It is most plentiful in vegetable oils and whole grains, but it is also present in green plants and meat and dairy products. The minimum daily requirement is 8 to 10 mg per day, although patients on total parenteral nutrition require about 50 mg per day. Doses of as much as 100 to 200 mg per kg body weight per day orally or 1 to 2 mg per kg per day intramuscularly are used to treat deficiency states due to malabsorption. Normal serum levels are between 0.5 and 2.0 mg per dl (0.011 mmol per liter). It is probably more meaningful, however, to measure vitamin E levels relative to the level of total lipids (normal greater than 0.6 mg per gram of lipid), as patients with vitamin E deficiency with normal absolute levels but low relative levels have been reported. Vitamin E works together with selenium to prevent superoxides from peroxidating polyunsaturated lipids in cell membranes.

The clinical syndrome associated with vitamin E deficiency usually resembles a spinocerebellar degeneration with ataxia, hyporeflexia, a loss of proprioception, and sometimes cerebellar tremor. Other manifestations are pigmentary retinal degeneration with or without visual loss, dysarthria and dysphagia, ophthalmoplegia, and dystonic posturing. Patients with Friedreich's ataxia and Charcot-Marie-Tooth disease have normal levels of vitamin E, but those with Charcot-Marie Tooth disease have been reported to benefit from pharmacologic doses of this vitamin. Vitamin E deficiency has also been associated with extensive morphologic change in muscle, usually without significant clinical weakness.

Because vitamin E is so abundant in a normal diet, dietary deficiency is almost unheard of, and deficiency is usually due to malabsorption. Such malabsorption diseases include chronic cholestasis, cystic fibrosis, the blind loop syndrome, short bowel, intestinal lymphangiectasia, and familial abetalipoproteinemia (the Bassen-Kornzweig syndrome). More recently a number of cases, often familial, of vitamin E deficiency have been found in the absence of a generalized impairment of fat absorption. It has been postulated that these patients have defective hepatocyte transport and release of vitamin E in newly synthesized lipoproteins.

Vitamin E has also been used as an antioxidant in the absence of deficiency, where its effectiveness is less well established. Some of these uses include preventing muscle cramps, preventing intraventricular hemorrhage in premature newborns, attempting to modify or reduce cellular damage caused by ischemia, reducing vasospasm from subarachnoid blood, and treating tardive dyskine-

sia. The use of vitamin E is also being studied in the treatment of Parkinson's disease on the theory that vitamin E might block a toxin postulated to be responsible for parkinsonism.

In summary, any patient with fat malabsorption, with clinical features resembling those of spinocerebellar degeneration, or with a pigmentary retinopathy should have a workup for possible vitamin E deficiency. Early treatment is important because patients may have early damage to the central nervous system even before symptoms develop, and once symptoms do develop, they are often not completely reversible by administering vitamin E.

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Diagnosing Duchenne Muscular Dystrophy

DUCHENNE type muscular dystrophy (DMD) is an X-linked recessive disorder characterized clinically by progressive proximal muscular weakness appearing at ages 3 to 5 years. A subsequent loss of muscle strength leads to wheelchair confinement by 11 to 12 years of age and early death due to respiratory failure. Duchenne type muscular dystrophy affects approximately 1 in 3,500 males. About 30% of cases appear to represent new mutations. Previously the diagnosis has been based on high concentrations of soluble muscle-specific enzymes, histologic evidence of widespread muscle degeneration and regeneration with fibrosis, a typical clinical course, and the family history. Two new techniques have recently been developed that permit a more specific diagnosis in both affected persons and carriers.

The DMD gene has been localized to the short arm of the X chromosome, band 21 region by studying affected persons who have other genome defects located in the same region. Using a technique known as restriction fragment length polymorphisms, a marker near the DMD gene was located; other diagnostic DNA probes within the DMD gene have since been identified. Prenatal diagnosis in women at risk is possible, with the test being informative in as many as 96% of women early in pregnancy. Later in pregnancy, the technique can be used on fetal tissue obtained with amniocentesis. These DNA probes now permit increased accuracy in genetic counseling and are most useful in detecting female carriers.

The entire gene has been cloned, and preliminary genomic organization is known. The gene is about 2 million base pairs with a high frequency of deletions. The gene product is a newly identified structural protein called dystrophin that represents about 0.001% of normal muscle protein. Dystrophin is less than 3% of normal levels in DMD phenotypes, low in the intermediate or outlier phenotypes, and of normal amount but of abnormal molecular weight in the Becker phenotype. In the near future, patients suspected of having either Duchenne or Becker's muscular dystrophy can be diagnosed with a muscle biopsy and an analysis of the dystrophin content.

While an accurate diagnosis of affected persons and carriers is now possible, the treatment of the disease remains unsatisfactory. The use of prednisone is being investigated, while recent experimental work in dystrophic chickens suggests that pure glucocorticoids such as dexamethasone may be more effective. These agents should be restricted to the experimental setting until the results of clinical trials now in progress are available.

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Recreational Drugs and Stroke in Young Adults

THE epidemic of drug abuse in our country has led to the reappearance of drug-related neurologic complications. If reports in the medical literature are used as a guide, it appears that the number of patients with drug-induced cerebral infarction or hemorrhage has been increasing over the past five years. In fact, drug abuse should be considered one of the more likely causes of stroke in these patients. Most of the popular street drugs, including cocaine, heroin, amphetamine ("speed"), and phencyclidine hydrochloride (PCP), have been implicated, and the types of strokes they cause may have devastating consequences. Moreover, stroke is only one of a number of severe neurologic catastrophes, such as toxic coma and status epilepticus, that may result from drug abuse.

One such stroke syndrome is intracranial hemorrhage. This may be due to rupture of an underlying vascular anomaly—that is, a berry aneurysm or arteriovenous malformation—or it arises from a vessel having no obvious preexisting abnormality. The hemorrhage usually occurs within minutes to hours after administering the drug (most often cocaine), and the clinical presentation is similar to that seen with "spontaneous" rupture of vascu-

lar malformations. The hemorrhage presumably results from the extreme hypertension and changes in vessel tone that result from the sympathomimetic properties of the drugs, although a direct effect of the drugs on vessel integrity has not been excluded.

Nonembolic cerebral infarction is associated primarily with amphetamine and cocaine abuse. Amphetamine may cause a diffuse angiitis of large vessels that appears as arterial "beading" on cerebral angiography. Cocaine use may also cause major vessel occlusion, although we have seen a few cases of infarction limited to the thalamus and midbrain, and there has been one report of the anterior spinal artery syndrome. There has yet to be a well-documented, unequivocal case of cocaine vasculitis, and it seems more likely that cocaine induces vessel thrombosis or focal spasm analogous to that seen in cases of cocaine-associated myocardial infarction.

Cardiocerebral embolus continues to be seen in cases of bacterial endocarditis due to intravenous drug abuse. Patients are also at risk of the rupture of mycotic aneurysms and subsequent subarachnoid or intracerebral hemorrhage, as well as the development of cerebral abscesses. Prolonged intravenous antibiotic therapy remains the mainstay of therapy.

These various stroke syndromes might be predicted to be more common with habitual heavy abuse and to depend on the route of administration. Our experience and that of others suggest this is not the case. Other than strokes associated with bacterial endocarditis, these syndromes have been seen in both first-time users and long-term abusers and by various routes—ingestion, inhalation, "snorting," and intravenous administration. Furthermore, street drugs are often mixed with or replaced by other compounds, such as lidocaine hydrochloride, that have their own neurotoxic effects.

Given the ongoing popularity of recreational drugs, practitioners need to consider drug abuse high on the list of potential causes of a stroke in a young person, and a drug screen should be a routine part of the workup. Programs aimed at prevention need to emphasize both the severe neurologic consequences and the extreme unpredictability that drug abusers face.

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Diagnosis and Treatment of Neurocysticercosis

THE recent increase in immigration from Mexico and other cysticercosis-endemic countries has increased the prevalence of neurocysticercosis in the United States. Patients may present with seizures (60%); increased intra-

cranial pressure with headache and papilledema (25%); and altered mental state with dementia and confusion (17%); focal neurologic findings with hemiparesis, paraparesis, and aphasia (12%); or no signs and the condition accidentally discovered (5%). A clinically useful classification system divides neurocysticercosis into active disease with cysticerci that are living or in the process of dying and inactive disease with cysticerci that are old and dead. The types of active disease include brain or spinal cord parenchymal cysts, arachnoiditis with or without hydrocephalus, brain infarction due to vasculitis, and mass effect due to a large cyst or cyst clumps. The types of inactive disease include brain parenchymal calcifications from dead cysticerci and hydrocephalus due to meningeal fibrosis.

The diagnosis of neurocysticercosis is most often made by computed tomography (CT). A CT scan in patients with active disease often shows one or more 5- to 20-mm diameter parenchymal cysts that may or may not show contrast enhancement of the cyst ring or hydrocephalus. Because intraventricular and subarachnoid cysts are often isodense with cerebrospinal fluid, they are difficult to recognize by CT. Nonionic contrast CT ventriculography may be needed to outline them. Early acute cysticercosis encephalitis may show diffuse brain swelling with or without multiple tiny foci of increased density representing the scoleces within cysticerci. A CT scan in patients with inactive disease often shows multiple 2- to 6-mm diameter scattered calcifications and occasionally hydrocephalus.

Magnetic resonance (MR) imaging in active disease shows both parenchymal and ventricular cysticerci as cysts with MR signal properties paralleling cerebrospinal fluid. Within the cyst a high-intensity 2- to 4-mm mural nodule containing the scolex may be seen. Administering gadolinium may show ring enhancement of the cyst. Dying cysts may be surrounded by a high-intensity rim of tissue edema. Racemose cysts in the subarachnoid space are larger and lack a mural nodule. Dead calcified cysts are difficult to recognize by magnetic resonance.

The detection of antibody against cysticercus antigens as measured by the enzyme-linked immunosorbent assay (ELISA) in the cerebrospinal fluid of patients with active disease has a sensitivity of more than 80% and a specificity of more than 90%. In serum the ELISA test has a sensitivity of 70% and a specificity of 50%. The Parasitic Disease Branch at the Centers for Disease Control, Atlanta, has developed a new immunoblot test that appears to have a sensitivity and specificity of close to 100%. False-negative tests occur most often in patients with few parenchymal cysts or inactive disease. Serologic tests appear to be most helpful in evaluating unexplained chronic meningitis or large atypical cysts. A biopsy of cysticercus subcutaneous lesions can provide a definitive diagnosis.

A regimen of praziquantel, 50 to 75 mg per kg body

weight per day in three divided doses orally for 15 days, is effective against living parenchymal cysts. Praziquantel is well absorbed from the gut, and free praziquantel in the serum rapidly enters CSF and cyst fluid. The drug is well tolerated, with the main side effects being gastrointestinal symptoms, headaches, and a decreased sense of well-being. Dexamethasone, 12 to 24 mg a day, or prednisone, 40 to 60 mg a day, is often given with praziquantel to reduce the transient worsening of neurologic signs or seizures that may accompany treatment. Praziquantel treatment cures or produces improvement in about 90% of patients with parenchymal cysts but in only about 50% of patients with arachnoiditis. In patients whose condition does not improve, retreatment should be considered with another regimen of praziquantel or with albendazole, 15 mg per kg per day in three divided doses by mouth for 30 days. Albendazole, a new drug not yet approved by the Food and Drug Administration, appears to be effective and also has few side effects. Inactive disease appears not to be affected by anticysticercosis therapy. Hydrocephalus often requires ventriculoperitoneal shunting.

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Thrombolytic Therapy for Acute Stroke

THROMBOLYTIC therapy following acute stroke is currently not recommended owing to the risk of cerebral hemorrhage. Clinical investigations before the computed tomographic (CT) scan era indicated that acute thrombolysis with exogenous agents such as streptokinase or urokinase promoted cerebral hemorrhage and clinical deterioration in patients with stroke. The difficulties encountered with those agents may have been due to several problems: the lack of CT to rule out intracerebral hemorrhage before treatment; an inadequate control of blood pressure; and the peripheral depletion of fibrinogen due to these thrombolytic agents, resulting in an anticoagulated state.

The development of recombinant manufactured tissue plasminogen activator (tPA) has reawakened an interest in using thrombolysis after an acute stroke. Tissue plasminogen activator does not promote a systemic lytic state as it is fibrin-specific; it is active on plasminogen only if bound to fibrin on the surface of a clot. Tissue plasminogen activator has a short half-life so that the thrombolytic effect can be controlled using a peripheral intravenous infusion. Intraarterial infusions are not necessary with the use of tPA as it is clot-specific.

To date, several necessary studies in animals to assess the safety and efficacy of tPA have been completed. Tissue plasminogen activator has been shown to effectively lyse emboli in the cerebral circulation of rats and rabbits. Thrombolysis as late as eight hours after a cerebral occlusion in animals is not associated with an increase in the incidence or size of cerebral hemorrhagic infarction. Administering tPA to animals within 45 minutes of cerebral ischemia appears to be effective in restoring neurologic function. Thus, from these preliminary studies, it appears that it is both safe and effective if administered promptly after a stroke occurs.

Clinical trials of the use of tPA are currently underway. The goal is to establish a safe dose to use in randomized double-blind studies of efficacy. Although there is great promise that ultimately tPA will be effective in patients with acute stroke, at present its use is restricted to the context of a research trial. In the large trials of administering tPA for coronary thrombosis, higher doses

are reportedly associated with an increased incidence of cerebral hemorrhage compared with lower doses. It is not yet clear whether these observations are accurate or what implications these findings have in the design of trials of tPA use for acute stroke.

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The Language of Medicine*

RICHARD A. SELZER, M.D.

COMMENCEMENT speakers are expected to utter stately sentences heaving with social and political significance or to give advice to graduates about the need to live blamelessly in an otherwise imperfect world. I am not going to do that. Nor am I going to tell you about the -ectomies and -ostomies of my life. Rather, I am going to celebrate that magnificent bequest that you have just inherited—the language of medicine, which is uniquely ours and must be given to only the most worthy.

I began to write at the age of 40, a fact that should encourage everyone in this audience. All at once, the “psychic energy” was available for this creative work, and I simply began writing. The first story I ever wrote was a retelling of the biblical tale of “Jonah and the Whale.” Because I knew firsthand what the gastric mucosa looked like, I could accurately describe Jonah’s new home. For the next three years, I attempted to learn how to write—to learn the craft of writing much as I had learned the craft of surgery. I made a vow to practice writing every day, which I diligently did between the hours of 1 a.m. and 3 a.m. During that time, I wrote horror stories. Surgeons *love* horror, and such stories are easy to write. My advice to any budding writer is to begin writing horror stories; they require no great philosophical profundity and no enormously complex character development. All that is necessary is the ability to make readers shiver.

For three years in the dead of night, I wrote horror stories, after which they began to be published in such eminent journals as *Ellery Queen’s Mystery Magazine*. I thought that I had died and gone to heaven. Eventually, a publisher from New York City telephoned me and said, “Do you have enough of those stories to make a book?” “Do I!” I said, and I backed the truck up next to his office. Out of that mass of horror, he selected 20 stories that he called *Rituals of Surgery*. The book had abso-

lutely nothing to do with surgery, but he thought that the title would enhance sales. He was wrong. Nevertheless, in due course, the book was available, and I was quite enamored with myself. I thought that certainly one day I would lie with Walt Whitman, Emily Dickinson, and the other great American poets.

About two weeks after the book was published, I was in the New Haven Public Library. The librarian behind the desk is an old friend of mine, inasmuch as I go there so frequently. Just ahead of me at the desk, returning (be still my heart) *Rituals of Surgery*, was one of those vestiges of Yankeehood, which may still be seen on the streets of New England towns and villages. Picket thin she was, without an ounce more of soft tissue than that absolutely necessary to hook ligament to bone, with an iron-gray bun impacted at her nape with a nail through it. Thinking to garner for me, within earshot, a most wonderful compliment, my friend the librarian said to this woman, “What did you think of that book?” Holding it between thumb and forefinger, as though it were moist and disgusting, she let it fall to the desk and said, “I would never let that man operate on me.”

That was my first contact with book reviewing. It was 3 o’clock in the afternoon. I went straight home to bed and pulled the covers over my head, and I didn’t get up until my wife fed me oatmeal with a long wooden spoon. I have since become somewhat tougher about that sort of thing, preferring to follow the suggestions of the immortal Tallulah Bankhead who said, “To hell with criticism, praise is good enough for me.”

Although I did not begin to write until I was 40, I may have long ago held the seeds of this interest. I grew up in Troy, Upstate New York, during the Great Depression. Father was a general practitioner; his office was on the first floor of the house, and we lived upstairs. In the windows of the first floor were plates of milk glass that announced the office hours—1 to 3 and 6 to 8 (which was ridiculous, because Father would have been delighted to see anybody at any time, and nobody had any money to go to a doctor anyway). During the hours of 1 to 3 and 6 to 8, my brother Billy and I were forbidden to speak out loud, lest we disturb the sacred rites that were going on

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downstairs. Out of sheer filial piety, I still have a little difficulty speaking out loud at those times of the day, but we will soldier today.

After 8 o'clock, when Father came upstairs for his supper, Billy, who was ten years old, and I, nine, would sneak down to his consultation room and go to the shelves where he kept his medical textbooks. It was there that I first became aware of the rich alliterative language of medicine. By the shame-faced light of a candle stub, we would take those books down, one after the other, to look at the pictures and read the words. Our favorite was the *Textbook of Obstetrics and Gynecology*.

I remember now that many of the best words that I read in those books began with the letter "c"—*cerebellum*. "Cerebellum," I said out loud, and let that word drip off the end of my tongue like melted chocolate. *Carcinoma*; it sounded rather like that aria from *Rigoletto* that my mother used to sing. Then I read the word that made a surgeon of me; *cholechojejunostomy*—all those syllables lined up, marching across the page, and ending in that terminal "y." I thought, if that is the way surgeons talk, I am going to be one of them.

Shortly after I retired from surgery, I was asked by the dean of the medical school at Yale to teach a seminar in creative writing to the medical students. Fifteen or so registered for the course, and every Monday night for 3 hours, we met in a conference room and wrote our little hearts out. Here in toto is what we learned. The students learned that a medical education ill prepares one for the rigors of writing. The students also learned the difference between "prostate" and "prostrate." It is no easy thing, I explained, to lie *prostate* upon the ground, even for those of us who have one. We learned that the word "disembosom" has nothing to do with breast surgery. This word is to be taken figuratively, as in "permit me to *disembosom* myself of a secret," which is altogether different from "disembowel," which has every right to be taken literally. We learned the difference between "prone" and "supine." Now, I accept that this is a fairly knotty problem inasmuch as the distinguished physician-writer Robin Cook, in one of his immortal novels, has an obstetrician instruct his nurse to place a woman in the prone position so that he might perform a pelvic examination. I would suggest that any woman so positioned should get up and get a second opinion. Overall, I was more than amply repaid for my efforts in that seminar when, at the end, one of the students told me that the philtrum, that sweet groove that runs from the nasal septum to the midpoint of the upper lip, is formed by the shushing finger of the angel who warns the newborn baby not to reveal the secrets of life before birth. I shall never again see a philtrum in the same way.

To acquire a love of language, one must know precisely what each word means, and knowing the origin or

derivation of a word helps even more. I shall give one example—the word "patient," which comes from the Latin *pator*, to suffer. Implicit in the word patient is suffering. Doctors have patients. Above all, this is what distinguishes us from lawyers, who have clients. "Client" comes from the Latin *cliens*, which is the term given to the vassals of a feudal lord for whom services, such as protection, were rendered in return for payment. We have patients; they suffer.

Before I retired, I was an amateur writer and therefore forgiven for all my sins. I was not a professional; I was simply a surgeon who wrote. Now, unfortunately, I am a professional and am taken to task for every little comma. When I was an amateur, I took great risks with the language, and if no word existed, I would fabricate one. I am in that very process right now, and I will tell you about it. All of you have seen a path of moonlight on the water. It is a sight that, each time it is beheld, nudges the mind along the loftier paths of romance and melancholy. This phenomenon, however, has no name—not in English, French, or Italian. Although nothing is wrong with "path of moonlight on the water," such a thing of beauty deserves its own word, and I mean to give it one so that all writers who come after me will know it and use it. After months of hithering and thithering, I have narrowed the possibilities down to two—path of moonlight on the water: "lunaqua" or "aqualune." At this point, I am leaning toward lunaqua because of the dearth of words in our language that end in "qua." I gave up trying to formulate a word for "path of sunlight on the water" when all I could propose was "aquadol," which is the name of a nasal decongestant.

Doctors are always making up words. Imagine that ancient Greek physician who thought to describe someone who was short of breath and fighting for air. From across the room, he heard the wheeze that marked each difficult exhalation and that seemed to be lodged deep within the chest of the sufferer. He called what he heard *asthma*. The word sounds like what it is—just as *hiccup* and *cough* do. Accordingly, the language has grown and enriched itself out of the need to describe. Not only doctors make up words. At the age of 21, Samuel Taylor Coleridge wrote to his chum: "Will you try to find a good servant, someone who knows about vaccimulgence." Vaccimulgence? Don't bother looking for it in a dictionary. Coleridge made it up. Nor has it, to my knowledge, ever been used since. It comes from the Latin word *vacca*, meaning cow, as in vaccination, and the verb *mulgere*, to milk; as in emulsify; so vaccimulgence is the milking of cows. One of my fondest hopes is to become the second person, ever, to use that word. For those of you who would race to your desks to beat me to it, I say it is no easy thing to use vaccimulgence in a sentence, artfully. Here are two examples that won't do: (1) I came

upon a pretty girl drowsy at her vaccimulgence and (2) he decided to become a veterinarian when first he experienced the joy of relieving cattle through vaccimulgence.

I will close now by reading a short story that I have written entitled "Vaccimulgence."

Even before she opened the barn door, Audrey knew from the sound of rhythmic hissing into a zinc pail exactly what she would see. Her husband, Roger, was sitting on a three-legged stool, his forehead pressed into the flank of a cow, absorbed in the tactile mysteries of vaccimulgence. It occurred to her that it had been years since he had touched her with anything near that tenderness. Either he had not heard her footsteps behind him, or he had and chose to ignore, whatever. Roger remained as he was and gave no sign. From where she stood, Audrey could see his elbows working, working. The metallic whine of the milk hitting the side of the pail was the most hateful sound of her life. At that moment, she could not have drifted from her purpose even had reason returned. No. She had come to the barn to kill, and kill she would. She was no more than 20 feet from where Roger sat when she raised the barrel of the shotgun and fired. At the blast, the body of the man was flung from the stool and then lifted into a crouching position. The sudden movement overturned the pail. In a

moment, the floor of the barn at his feet was running with blood and milk. And slowly, as in a dream, he turned down to gaze at the lifeless body of his beloved cow. "Elsie," he sobbed, "why? why?"

"She had it coming," said Audrey, "but I could never expect you to understand that."

All of which brings me to the end of this commencement address, so called, the place where I must say the last word. Should it be "Amen" or "so be it"? Despite what the dictionary says, they do not mean the same thing. "So be it" carries with it an air of acceptance of resignation. It is a quiet term, murmured with the head bowed—"so be it." More often than not, "Amen" is a word shouted in jubilation, especially when the first syllable is prolonged and the second is cut short, as in "Aah-men." Looking back, I see that I have many more "so be its" to my credit than "Amens," which is not the way I had hoped things would go. So just to help even the score and because it so perfectly fits this grand occasion, I hereby call out "Amen."

Abuse of Children, Elderly Persons, and Others at Risk

Laws that require the reporting of cases of suspected abuse of children and elderly persons often create a difficult dilemma for the physician. The parties involved, both the suspected offenders and the victims, will often plead with the physician that the matter be kept confidential and not be disclosed or reported for investigation by public authorities.

Children who have been seriously injured, apparently by their parents, may nevertheless try to protect their parents by saying that the injuries were caused by an accident, such as a fall. The reason may stem from the natural parent-child relationship or fear of further punishment. Even institutionalized elderly patients who have been physically maltreated may be concerned that disclosure of what has occurred might lead to further and more drastic maltreatment by those responsible.

The physician who fails to comply with the laws requiring reporting of suspected cases of abuse to children and elderly persons and others at risk can expect that the victims could receive more severe abuse that may result in permanent bodily or brain injury or even death.

Public officials concerned with the welfare of children and elderly persons have expressed the opinion that the incidence of physical violence to these persons is rapidly increasing and that a very substantial percentage of such cases is unreported by hospital personnel and physicians. An important element that is sometimes overlooked is that a child or elderly person brought to a physician with a suspicious injury is the patient whose interests require the protection of law in a particular situation, even though the physician may also provide services from time to time to parents or other members of the family.

The obligation to comply with statutory requirements is clearly stated in the Principles of Medical Ethics. It should be noted that the ethical obligation of the physician may exceed the statutory legal requirement.

— AMA Council on Ethical and Judicial Affairs

Health Care Needs of Homeless and Runaway Youths

AMA COUNCIL ON SCIENTIFIC AFFAIRS

Large numbers of homeless adolescents can be found in this country, with estimates of their numbers ranging from 500 000 to more than 2 million. Some are runaways while others are involuntarily without shelter, often having been forced out of their homes. Most receive no help from social service agencies and their lack of skills forces them into a marginal existence, leaving them vulnerable to abuse and victimization. Health problems are numerous and health care is generally inadequate for several reasons, including a lack of treatment facilities, the behavior of the adolescents themselves, the ability of providers to deal with such youths, and the questionable legal status of homeless adolescents. The Council on Scientific Affairs urges that reliable and up-to-date data on the extent of homelessness among adolescents and the nature of their needs be generated and that guidelines for the medical care of such youths be developed.

LARGE numbers of homeless and runaway adolescents roam the streets of every major city in this country. However, little is known about them, their needs, or their experiences. In fact, the issues surrounding homeless adolescents generally are either ignored or altogether unknown, and, when acknowledged, are most often discussed in terms of homeless families with children, not as independent youths with no homes to which they can return. Much of what is documented about such youths can be found in movies such as *Streetwise* and *Pixot*, both of which are available in video form, or in newspapers and magazines such as *Parade* (July 20, 1986;4-6).

The problems of the homeless are probably similar regardless of age, and the American Medical Association previously reported on health care needs of the homeless in

Board of Trustees Report LL (1986 Annual Meeting). In this report the discussion is focused on adolescents.

Like estimates of the homeless population in this country,^{1,2} estimates of the number of homeless and runaway youths vary widely. Most of the work in this area has focused on runaways; almost none has examined other homeless adolescents. Using data collected in a probability sample of US households, the number of runaways in this country has been estimated to be between 519 000 and 635 000 annually.³ Others have estimated the number of runaways to be at least 1 million annually and perhaps in excess of 2 million.⁴ Most runaways return home within a week, but substantial numbers stay away longer. One in 20 is estimated to be gone for more than a year.⁵ Corresponding figures for homeless youths are rare. Robertson⁶ indicates that there are 1 million adolescents living on the streets, most of whom do not receive help from any service agency. Shaffer and Caton⁷ estimate that about one half of 1% of New York City's teens between the ages of 12 and 17 years use a shelter annually. If applicable to the entire country, this means that more than 100 000 adolescents in this age group sleep overnight in a shelter in a 1-year period. However, most authorities agree that adolescents are relatively unlikely to use shelters, preferring instead to stay on the streets or with friends and relatives.

The extent to which the populations of homeless adolescents and runaways overlap is unknown, partly because there are no commonly agreed upon definitions of these terms. *Runaways* are most often thought as having voluntarily left their homes, choosing to live apart from their fami-

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This report is not intended to be construed or to serve as a standard of medical care. Standards of medical care are determined on the basis of all of the facts and circumstances involved in an individual case and are subject to change as scientific knowledge and technology advance and patterns of practice evolve. This report reflects the views of scientific literature as of November 1988.

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Members of the Council on Scientific Affairs are as follows: Scott L. Bernstein, Champaign, Ill, Medical Student Representative; George M. Bohigian, MD, St Louis, Mo, Chairman; Yank O. Coble, Jr, MD, Jacksonville, Fla; E. Harvey Estes, Jr, MD, Durham, NC; Ira R. Friedlander, MD, Chicago, Ill, Resident Representative; William R. Kennedy, MD, Minneapolis, Minn; Patricia J. Numann, MD, Syracuse, NY; William C. Scott, MD, Tucson, Ariz, Vice Chairman; Joseph H. Skom, MD, Chicago, Ill; Richard M. Steinhilber, MD, Cleveland, Ohio; Jack P. Strong, MD, New Orleans, La; and Henry N. Wagner, Jr, MD, Baltimore, Md; William R. Hendee, PhD, Chicago, Ill, Secretary; William T. McGivney, PhD, Chicago, Ill, Assistant Secretary; and Roger L. Brown, PhD, Chicago, Ill, Senior Scientist and Staff Author.

lies. *Homeless adolescents* would probably be regarded as those who are involuntarily without shelter.⁸

These distinctions, however, are at best artificial. At worst, they contribute to the lack of understanding surrounding issues of teen homelessness. Adolescents are more likely to consider themselves homeless than they are to regard themselves runaways. For example, among 118 runaways (legally defined) in New York shelters, 56% considered themselves either homeless or both runaway and homeless,^{7,8} that is, they have no home to which they feel they are able or willing to return. Furthermore, the likelihood of defining oneself as homeless increases with age,⁸ although this is influenced to some extent by the fact that, by most legal definitions, one's status as a runaway ends at age 18 years.

A number of investigators report that large numbers of adolescents are the victims of abuse at the hands of their parents or guardians, and many leave home for this reason.⁷⁻¹³ Other homeless youths have been rejected by their families. Gulotta,⁹ for example, reports that nearly one fourth of the youths in a shelter for runaways were forced out of their homes by their parents and nearly one half were teens who had been unable to find satisfactory arrangements through a state or local social service agency. Under such circumstances, it can hardly be surprising that many homeless adolescents consider themselves homeless and not runaways.

Health Care Needs

Like other people, homeless adolescents occasionally need medical treatment. However, issues of money, permission, and confidentiality frequently conflict with a youth's need for treatment, and access to care is generally difficult. As a result, medical care is frequently unavailable, and delays in seeking treatment are common. The hazy legal status of minors also precludes prompt and full treatment.⁵

Under these circumstances and because homeless youths frequently suffer from multiple physical complaints, guidelines for use by physicians when treating such youths could be extremely useful. However, such guidelines are virtually nonexistent. To date, we have found only one shelter that has assembled a protocol for the management of the complaints that homeless and runaway youths are likely to present, and that protocol is used only in the medical van operated by the shelter.¹⁴ If guidelines were available, they could ensure that the needs of such youths are addressed and would help standardize care among a group for whom care is most often hit or miss.

The health issues surrounding homeless youths are not unlike the health issues facing the homeless population in general. At the same time, adolescents tend to be somewhat more healthy by virtue of their age and the fact that the average time they have been on the streets is less than it is for homeless adults. The health problems faced by homeless adolescents can be grouped into six

areas as follows: nutrition, substance abuse, psychiatric problems, physical complaints (especially those related to exposure and hygiene), sex-related medical concerns, and problems associated with victimization and abuse.

Nutrition

Just as it is for the homeless population in general, the supply of food is often inadequate for homeless adolescents. Nutritional deficiencies are common in the homeless population,¹⁵ and large numbers of runaways have difficulty meeting this basic need.¹⁶ Clinics that serve runaway and homeless adolescents frequently note the inadequate nutrition of their clients (*Medical Tribune*, November 21, 1984:1; *Family Practice News*, February 15, 1986:3). This situation also has frightening implications for the health and well-being of children born to homeless adolescent females, among whom pregnancy is fairly common.

Substance Abuse

Compounding problems caused by inadequate nutrition are high rates of alcohol and drug abuse among these youths. Large numbers of runaways reportedly drink regularly, and up to one half have diagnosable alcohol problems.⁵ The abuse of other drugs is also common, especially in the central parts of major cities where homeless youths are likely to congregate. For example, in a study in New York City, 70% of the runaways admitted to using illegal drugs, and some admitted to being addicted.⁷ Most substance abuse programs do not have adolescents in their programs, and the majority, in fact, exclude adolescents.

Mental Health

Closely related to the problems of substance abuse are high rates of psychiatric disturbances among homeless youths. Most research on the homeless mentally ill has focused on the effects of deinstitutionalization in adults, but homeless adolescents are also afflicted by mental health problems. Large numbers of adolescents in the general population are affected by such problems¹² and, given the difficulties of life on the street, it is likely that relatively more homeless youths suffer psychiatric illnesses. Furthermore, adolescents are less likely than adults to have ever received care in the mental health system, a situation that will certainly not improve among homeless adolescents.

According to researchers, the most common mental health problems in homeless adolescents are depression and self-destructive behavior, including suicide.^{7,8} Anti-social behavior is also commonly reported,⁷ although it is unclear whether runaways are more likely to engage in such behavior or whether those who commit antisocial acts are more likely to run away. A number of researchers argue that running away is a coping mechanism for troubled adolescents.^{16,17} If correct, it seems likely that runaways are coping with their prior behavioral problems by running away and that later antisocial acts are a continuation of previously established behavioral patterns.

Physical Health

Physical health problems are also common in this population. Living on the streets not only subjects these youths to otherwise avoidable stressors such as the weather, but it also poses difficulties for routine tasks associated with personal hygiene. Exposure to the elements, the lack of sleeping quarters, and the absence of a clean domicile all contribute to physical ailments.

The most commonly reported ailments in this group are general malaise and musculoskeletal, gastrointestinal tract, and genitourinary problems (*Medical Tribune*, November 21, 1984:1).⁵ Injuries such as broken bones are not infrequent. Among homeless children under 16 years of age who were seen by medical providers as part of The Robert Wood Johnson Foundation/Pew Memorial Trust Health Care for the Homeless program, the most common complaints were upper respiratory tract infections, minor skin ailments, and gastrointestinal tract problems.¹⁸ Unfortunately, in the data from this program, older adolescents are included in a category that encompasses those up to age 29 years, so information on adolescents is not available.

Sexual Health

Included in genitourinary disorders are both pregnancy and sexually transmitted diseases. Runaway and homeless youths are without doubt sexually active, possibly more so than other adolescents. Data from a decade ago suggest that, on average, runaway girls experience intercourse 2 to 4 years earlier than teenaged girls who live at home.¹⁹ Moreover, large numbers of adolescent homeless girls become pregnant. Shaffer and Caton⁷ found that one third of the female runaways they interviewed either were or had been pregnant at least once. In the Health Care for the Homeless program's first year, nearly one fourth of the females aged 16 to 19 years were pregnant at the time of their first visit to a physician or became pregnant during the next year; the figure for those who had ever been pregnant would be even larger.¹⁸ Of course, figures for those ever pregnant are inflated somewhat by the fact that some girls run away or are thrown out of their homes after they become pregnant. Contraceptive use among such youths is uncommon.⁷

Sexually transmitted diseases are common in both boys and girls. Data from runaways held in Los Angeles detention facilities indicate that about one third of the girls have some venereal disease at the time of their detention,⁵ but this figure may be high since other researchers have reported rates that are closer to the rate for the general population, about 1.5%.^{7,18}

Among the sexually transmitted diseases, there is special concern about the acquired immunodeficiency syndrome. The human immunodeficiency virus has a mean incubation period of 8 years,²⁰ so many 20- to 29-year-olds with acquired immunodeficiency syndrome must have become infected in their teens. Furthermore, a significant number of homeless youths report having

engaged in homosexual encounters,^{5,21} a risk factor for human immunodeficiency virus infection. With their high levels of sexual activity, homeless youths are at high risk of both becoming infected and transmitting the virus.

Victimization

Another factor related to the level of sexually transmitted diseases among homeless adolescents is the degree to which they are victimized by others. Nearly two thirds of the runaway and homeless youths studied by Kufeldt and Nimmo¹⁶ had been approached and asked to engage in some illegal activity. (These authors did not collect data on the level of participation in such behavior because of concerns about confidentiality.) Unfortunately, their lack of marketable skills and their status as minors leave homeless youths with few legitimate alternatives to illegal activities. Participation in these activities, however, subjects them to a variety of risks, including disease and both physical and psychological trauma.

Large numbers of homeless adolescents are involved in illegal drug trade, prostitution, and pornography and many were subjected to sexual or physical abuse before they became homeless.¹³ Some 900 000 youths, two thirds of whom are female, are involved in prostitution; their average age is 15 years.¹² Nearly four fifths of adolescent female prostitutes may be runaways, and a sizable number of young male prostitutes are runaways as well.⁵

The role that prior victimization plays in creating runaway youths who consider themselves homeless cannot be overstated. Teenage girls have frequently been sexually abused by family members in their homes,¹³ and physical abuse is also common. Indeed, the level of physical abuse in runaways has been reported to be as severe as among adolescents under the care of child protective services or seen in hospital child abuse clinics.^{22,23}

Providing Health Care

Providing treatment for the health problems of homeless adolescents is complicated by the very behaviors associated with homelessness. Most of these youths believe that without the money to pay for treatment, medical care is unavailable to them. Additionally, most homeless adolescents are untrusting of authority figures such as physicians, delay seeking medical attention until problems become so severe that help seeking can no longer be postponed, and neglect to return for follow-up care (*Family Practice News*, February 15, 1986:3).⁵

While little can be done about the latter two factors, some authorities have suggested that health care providers could improve their interaction with youths and thereby improve compliance and encourage return visits. In general, providers are advised to treat such patients in as nonjudgmental and nonthreatening a way as possible to encourage the patient to fully discuss his or her health complaint and the reasons for his or her homelessness. Insofar as possible, maximum treatment should be given

at the initial visit since the adolescent's return cannot be expected with any certainty.^{5,24} In addition, some advocates for runaway youths believe that health care providers should form linkages with programs that serve youths so that they can become knowledgeable about the particular needs of such youths and aware of resources in their locales.

Legal Considerations

Notwithstanding the efforts of individual providers, significant barriers to treatment remain because of the questionable legal status of homeless adolescents. Board of Trustees Report LL noted that adolescents who are outside the guardianship of a family are often barred from health care by the inability to give legal consent as well as by the lack of documentation that would enable them to qualify for public assistance programs.

At the same time, all states allow some care to be provided to minors without parental consent under certain, often specialized, circumstances. For example, under Illinois statutes a physician can provide care to minors who are married or pregnant and can render emergency treatment to a minor if, in the sole opinion of the physician, obtaining consent is not reasonably feasible under the circumstances.²⁵ Nearly all states allow minors to be treated for venereal disease without parental consent, and both federal and state laws have been enacted to permit children to receive treatment for such problems as drug and alcohol abuse without parental consent.²⁶

Similarly, providing counseling services to a minor without the consent of his or her parents is more than likely permissible. Liability would probably be limited to those cases in which the care is so outrageous as to be "beyond any tolerable boundaries of human conduct."²⁶ In fact, in the case of counseling by a mental health professional, there are no reported cases of liability for providing care to a minor without parental consent.²⁶

Several states also have passed laws defining emancipated minors—a status that probably applies to many homeless adolescents. These laws permit adolescents to consent to medical treatment if the physician provides full disclosure and ensures the patient's understanding of the procedure and its consequences. In general, an emancipated minor is living apart from his or her parents, with or without their consent and, in addition, is self-supporting and managing his or her own financial affairs.²⁷ Where specific legislation has not been enacted, arguments for emancipated minors can be found in common law.²⁶ Youths meeting the definition of an emancipated minor may be able to consent to treatment. According to Croxton et al,²⁶ there are no reported cases imposing liability on a physician or hospital for failing to obtain parental consent where the minor was at least 15 years old.

Recommendations

Experts generally agree that homelessness among adolescents is increasing. However, data on the extent of the

problem of homelessness in adolescents are sorely lacking. For example, the number of such youths is unknown, knowledge of their health care needs is based more on speculation and anecdotal information than on hard data, and differences between the adult and adolescent homeless populations are glossed over. Virtually nothing is known about the needs of subgroups within the adolescent homeless population or about what happens to these youths as they age. Undoubtedly, some of these children die on the streets.

In addition, few specifics are really known about the health care needs of these youths. Medical care for homeless adolescents is generally considered to be inadequate for a variety of reasons, including a shortage of facilities, the behavior of the adolescents themselves, the ability of providers to deal with such youths, and legal complications of providing treatment, but, again, there is a dearth of scientific data on these issues. For those youths who do not come into contact with service providers or agencies, there is little information on treating their needs. Guidelines for the treatment of such youths are virtually nonexistent, and those guidelines that do exist are not widely known. These issues merit close study.

In view of these conditions, the Council on Scientific Affairs recommends that the American Medical Association do the following:

1. Urge that a national study that would provide accurate, timely, and reliable data on homeless adolescents be funded by an appropriate government agency.
2. Consider conducting a pilot study of the health care needs of homeless youths in a major city to provide physicians with solid baseline data on this issue.
3. Explore the feasibility of establishing a protocol to be used in the evaluation and treatment of homeless youths.
4. Disseminate information on the lack of treatment facilities and health care providers for treating homeless youths.
5. Encourage state medical societies to determine the extent of treatment possible under state laws, to inform physicians of the laws and regulations affecting the treatment of minors, especially those who are homeless, and to form linkages with statewide youth advocacy groups to develop protocols for the treatment of troubled youths.
6. Encourage local medical societies to develop and publicize lists of local and regional resources that can assist homeless adolescents, to provide this information to local physicians, and to establish links with providers of youth services to improve knowledge of the needs and limitations of the youths themselves and physicians who provide care.

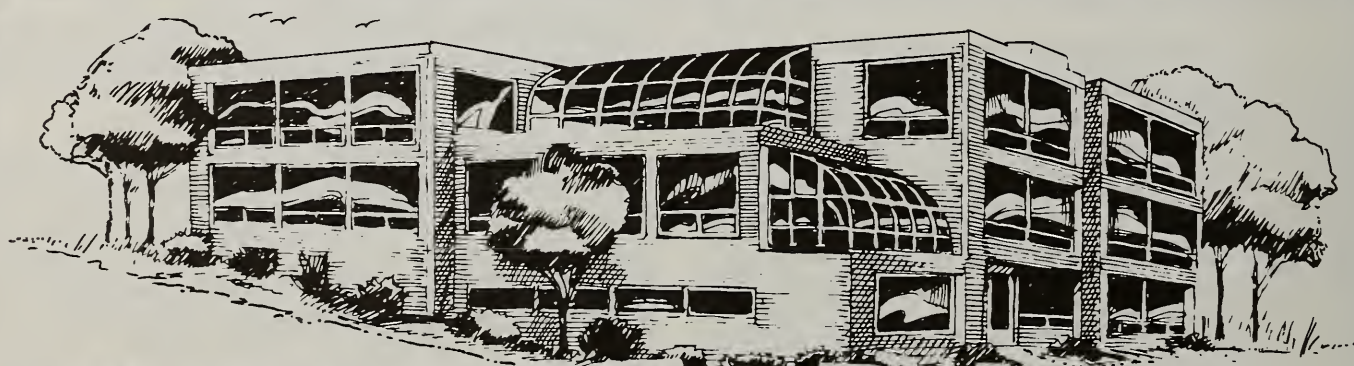
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Fifty Hours for the Poor?

LEIF C. BECK, LL.B., CPBC

IN the December 1987 issues of the *American Bar Association Journal (ABAJ)* and the *Journal of the American Medical Association (JAMA)*, there appeared a joint editorial. It urged both attorneys and physicians to give some of their time and talents to care for the poor, recognizing that not enough do so "in a voluntary and uncompensated way."¹

The editors' effort to prod lawyers' and doctors' social consciences did not represent official AMA or ABA policy. Medical societies, at least, gave the idea some official lip service and a variety of self-serving recitals about doctors' long-standing service. Then the idea faded away, where I suspect most doctors prefer it stay: "Out of sight, out of mind."

Medical societies probably reflect their members' views on this issue. Besides, professional organizations can better deal with larger scale *organizational* responses to problems, like pressing for increased Medicaid fees so the poor will receive more — or perhaps more enthusiastic — physician care. The gist of the *ABAJ/JAMA* editorial, however, was a *personal* appeal to each individual — not to their medical societies.

Individual Conscience

As a medical management consultant, I see hundreds of physicians yearly. I delve into their attitudes towards medical practice, their philosophies about patient care, and even their general value judgments. Furthermore, through medical society meetings, speeches, and exhaustive reading of medical journals, I believe I have a solid picture of physicians' attitudes.

The picture is not as good as either you or I would like it to be. Many doctors, of course, have true service attitudes transcending their roles in the business of providing medical care. Almost all strive for excellence in technical care, with pride that their work generally helps people while it also builds economic success. But a pervading attitude — usually kept out of sight and out of mind — cannot withstand truly critical evaluation.

This prevailing view is totally contrary to the idea of

giving just "50 hours for the poor." The attitude is based on what is done within a physician's general work pattern, rather than what is provided from the heart. All-too-common examples of physicians' rationalizations include:

- "I give away so much free service by accepting less than full fees from Medicare and Medicaid, for the aged and indigent." While accepting Medicare assignment and treating Medicaid patients represent a financial concession, it is hardly like deliberately caring for the poor in a "voluntary and uncompensated way." I know too much about physicians' strategies in setting fees and handling Medicare/Medicaid to believe that this is truly charitable.

- "I care for a variety of no-fee patients. They're the nonpaying dead-beats, drug addicts, and winos coming through my practice." The very statement, which I have heard a number of times, contradicts a sense of charity right on its face.

- "I take my turn in the hospital's weekly (or monthly) free-care clinic, thus serving those unable to pay my practice's fees." It is obviously good that these clinics exist, serving whatever patients find their way to them. But I also know how many physicians take comfort in sending patients from their private offices to the clinics in order to get them out of the way.

- "All the technical equipment for my specialty care is in my office, and poor patients don't come here." The poor probably are not aware that you even exist, of course, much less that you want to care for them if they find their way to your office. Expressing a willingness to do what no one knows to ask for is not very charitable.

Back in December 1987 I wrote an article entitled "Questioning the Physician's Broader Responsibility."² It put the issue of offering free care in spiritual terms. Rationalizations like those above will not hold much water in Judeo-Christian thought, nor in virtually any other established religion.

And, as noted, they contradict the *professional* obligations suggested by the *ABAJ/JAMA* editors as well. How, for example, can one justify the described rational-

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izations against these excerpts from the *ABAJ/JAMA* editorial:

The privilege to practice law or medicine has carried with it the obligation to serve the poor without pay. Doctors and lawyers today have tended to become overly concerned with their professional incomes and practice efficiencies, but they must not forget higher duties...

The philosophical and ethical roots of the medical and legal professions are entwined with the public interest, service to the community and caring for the poor. These professions maintain those values.

Whether you approach it spiritually or professionally, the issue is before you as an individual. It is the same as each other person must consider, whether or not a physician, but doctors have a unique opportunity to serve. Rather than being a burden, as some physicians protest it, the ability to give "hands on" service to people in need is a real blessing. Would that we nondoctors could operate on a blind woman so she could see again on a Project Hope third world venture or help a sickly child on an impoverished Indian reservation.

Busy Practices

The demands of successful medical practice make it even more difficult to answer the call for 50 hours. Physicians have written me that there are so many patients to be seen and referrals to be honored that there is no time to give away to another obligation. How, they ask, can one give time for the poor when they're already overwhelmed by their for-profit practice.

The question itself suggests an answer, but it is one very few people are willing to give. That answer is to carve time out of your busy schedule for free care of the poor — *even if* it means seeing that many fewer patients and earning that much less income. After all, nothing *requires* you to take every paying patient who wants to see you.

This answer bumps right into any ambitious professional's work ethic. He or she feels obligated to serve each patient who presents for service. Perhaps even more compelling, he or she cannot afford to turn away even one referred patient out of fear that the referrer will then start a different pattern.

While sympathizing with these concerns as a fellow-professional, and as an advisor to physicians, I concluded several years ago that they are more imagined than real. One's practice will not fall apart if he or she downsizes it slightly in an orderly way. And, surprisingly, one rarely loses much income even if he or she restructures practice time to accommodate another distraction.

Besides, many physicians are *less* busy than they would like to be. Statistics showing the decline in average number of office visits per week, for instance, show this point. For each doctor who is fully booked, I know of another doctor with holes in his schedule. A physician

who is not overbooked could rearrange his or her schedule for special sessions in alternate environments.

The income question is obviously a thorny one. No one — whether physician or not — wants to compromise his or her income-producing ability. And yet I see doctors day in and day out who say they never expected to earn as much as they do; they are almost embarrassed by their affluence.

Not so embarrassed, though, to walk away from their income levels. All of us find that our living and spending patterns quickly adjust to our incomes, upon which our luxuries become our necessities. A look in hospital doctors' parking areas makes one wonder if all the luxury autos are necessary. Could the doctor driving a top-of-the-line Mercedes instead have spent 50 hours for the poor and driven a Honda Accord?

Group practice makes it still more difficult to deflect time for nonpaying service. I advise clients that the *group's* success must be a higher priority than any of its members' interest. How, then, can a group accommodate a member who will produce less than his partners because he insists on serving the poor? The question has strained some groups to the breaking point, although there are notable examples of accommodation.

Many law firms have answered this group practice issue with the idea of *pro bono* service — each member's providing group-supported service to nonpaying causes as part of the group's overall professional obligation. Medical group practices have not typically taken such policy positions, but perhaps they should do so. After all, the conscience of a five-physician group may be better formed and enunciated than a solo doctor's decision-making process. And larger groups should be able to accommodate *pro bono* service spread among those members who feel particularly compelled to provide it.

Questions Often Avoided

In effect, none of us — neither physicians nor other professionals including me — really want to address these questions because they interfere with our comfort zone. If asked at all, it is usually satisfactory to accept easy answers like:

- "I serve through Medicare and Medicaid writeoffs."
- "I serve the poor by accepting their nonpay excuses."
- "I take my turn in the hospital clinic."
- "My practice is overwhelming me with regular patients and referrals."
- "I can't afford to reduce my income by taking fewer paying patients."
- "My group can't accommodate my doing less than my partners do."

It's like attending a church sermon. The minister asks tough questions and suggests how our religion would answer them. We nod in agreement, see how those answers bump into our own realities, and then we tell the minister he gave a good sermon!

That is not what the *ABAJ/JAMA* editors had in mind. While no one has contradicted their "50 hours for the poor" call, no one seems to be picking up on it, either. Out of sight, out of mind!

How to Serve

Some doctors have truly expressed a desire to serve but felt unable to find a means for doing so. A number of physicians have replied to my editorials on this theme by asking me what to do.

To begin with, the answer must come from within the individual. He or she must have a "mindset" that fosters an affirmative way to *seek out* service opportunities, even to *create* them where they do not already exist. You cannot honor the "50 hours" call by waiting for an opportunity that perfectly fits your existing practice life.

A neurologist, for example, asked how he could provide his specialty service in underserved area clinics when his specialized equipment is back in his regular office. One solution would be to schedule some hours at the inner-city facility and take those patients needing more extensive service back to his office for a follow-up visit, having qualified them as being "needy." Many other specialists could follow this pattern, taking only their skills and any basic transportable equipment to screen for patients having complaints touching on their expertise.

Family practitioners, internists, pediatricians, and obstetrician-gynecologists do not even have this concern. The need for medical service should find an outlet for "hands-on" care somewhere around, in addition to their private offices. The larger cities certainly have such clinics needing physician help, and they can be sought out elsewhere throughout the state.

Service to the poor need not be limited to nearby low income areas. Your next vacation, perhaps extended for several extra weeks, could be in the "third world" countries of Central and South America, Africa, or Asia where literally millions of people need your talents. Even if you alone cannot make a dent in the world health picture, each person you treat and help is a wonderful contribution. And isn't that — caring for people one-by-one — a basic principle of medicine, anyway?

Question of Attitude

The point is that "50 hours for the poor" is a challenge to each individual physician's personal *attitude*. To answer it, you have to affirmatively seek out special ways to use your abilities. You cannot sit back and repeat the litany of reasons why the challenge may not apply to you.

Besides, the apparent sacrifice of precious time, energy, and (maybe) income can really enrich your life. One doctor who has participated in a number of voluntary service programs put it this way:

Those physicians who do voluntary service, whether in their own locality or on an international basis, find that their satisfaction with their work and with life increases; and those who involve their families in this work find that their family relationships are nurtured.

Financial Contributions

Donating money to worthy causes is not really a substitute for giving time and energy. Writing a check involves no deflection from one's regular routine of successfully practicing medicine. And if a successful physician's income has reached the normal levels for his or her specialty, even a fairly generous check will not adversely affect his or her present or future lifestyle.

And yet physicians have a notorious reputation as "cheap" when it comes to charitable contributions. This is partly because doctors are generally "income-rich, but wealth-poor." After modest beginnings, often in debt, those with thriving practices achieve enviable annual earning levels before they accumulate enough wealth to assure future security.

Still, perhaps physicians as a class could and should be more generous financial contributors. This is also a matter of *attitude* — a question of the heart and the spirit, more than of reciting seemingly valid reasons for saying "no." As just one example, while doctors often give generously to the hospitals in which they practice, I know that those "gifts" are a near requirement of active practice — more like business expenses than truly charitable donations.

Many organizations offering health services to the poor need funding as well as on-site physician presence. What better use for doctors' contributions than to fund those physicians and organizations trying to care for people who fall through the gaping cracks in our country's health care system?

Helping to finance medical students' and residents' education fits right into the idea of directing the fruits of your success back into individuals' needs within the profession.

Conclusion

"Fifty hours for the poor." One hour a week, or four hours each month, is a minimum call for physicians and lawyers. Bar associations foster *pro bono* public service law, as honored by many law firms and individual attorneys. For physicians, it is left more to the individual for whom it can too easily be rationalized out of sight.

But giving your time, talent, and money for people in real need matters in many ways. Your profession calls for it, many unfortunate people will benefit from it, and the volunteer is spiritually and morally strengthened by the effort. Though not just a religious concern, one minister put it this way about physicians:

The knowledge they have and the talents given them are things that they have been given by God. They owe much to God and need to return much.

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Debut of a Somatostatin Analog: Octreotide in Review

LEAH R. ZINDEL, R.Ph.

ABSTRACT—Octreotide is a long-acting cyclic octapeptide with pharmacologic actions mimicking those of the natural hormone somatostatin. It can suppress the secretion of serotonin, as well as the gastroenteropancreatic peptides gastrin, vasoactive intestinal peptide (VIP), insulin, glucagon, secretin, motilin, and pancreatic polypeptide. It also suppresses growth hormone and decreases splanchnic blood flow. Octreotide is completely and rapidly absorbed following subcutaneous injection and has an elimination half-life of 1.5 hours.

Clinical trials reviewed here show octreotide useful in the treatment of diarrhea associated with VIP secreting tumors, as well as diarrhea and flushing associated with carcinoid syndrome, both conditions for which the drug is approved. Clinical trials involving the use of octreotide in the treatment of acromegaly are also reviewed.

Adverse reactions to octreotide are mild to moderate and most commonly involve injection site pain and diarrhea. Drug interactions are apparently related to the drug's pharmacologic effects.

Octreotide is given subcutaneously two to three times daily, with daily doses ranging from 50mcg to 1,500mcg per day. Further research appears necessary to clarify dosing issues.

Introduction

THE somatostatins are naturally occurring polypeptide substances with a number of biologic functions. Present in almost all types of organisms, they are described as being evolutionarily ancient and possibly unchanged for over 400 million years.² No single stimulatory or inhibitory function has been ascribed to the somatostatins; they have been observed to affect a wide range of gastroenteropancreatic peptides as well as serotonin and growth hormone (GH).

Octreotide is a long-acting cyclic octapeptide with pharmacologic actions mimicking those of the natural hormone somatostatin. It is indicated for the treatment of severe diarrhea and flushing associated with metastatic carcinoid syndrome as well as diarrhea associated

with vasoactive intestinal peptide - secreting tumors (VIPomas).¹

Pharmacology

Pharmacologically, octreotide has specific advantages over native somatostatin; it is absorbed from subcutaneous sites, it has sustained action due to reduced susceptibility to metabolic degradation, and it is in general three to 23 times more potent than somatostatin-14.³ Octreotide exerts a multitude of pharmacologic actions similar to the natural hormone somatostatin. It can suppress the secretion of serotonin as well as the gastroenteropancreatic peptides gastrin, vasoactive intestinal peptide, insulin, glucagon, secretin, motilin, and pancreatic polypeptide. Octreotide also suppresses GH and decreases splanchnic blood flow.¹

While octreotide essentially mimics the actions of somatostatin, it is a more potent inhibitor of GH, glucagon, and insulin than the natural agent. Octreotide is especially selective toward GH and glucagon suppression.¹

Pharmacokinetics

While octreotide is poorly absorbed orally, it is completely and rapidly absorbed following subcutaneous injection. Peak concentrations of 5.5mg/ml (5.4nmol/L) were reached within 25 minutes following a 100mcg dose. Peak concentrations and area under the curve values are dose proportional following either single subcutaneous or intravenous (IV) doses up to 400mcg and with multiple doses of 200mcg three times daily. Clearance appears to be reduced at higher doses, suggesting nonlinear kinetics at daily doses of 600mcg per day as compared to 150mcg per day.

The distribution of octreotide from plasma is rapid. The volume of distribution is approximately 13.6 liters. In the blood, the drug is about 65% plasma-bound.

The elimination half-life of octreotide is approximately 1.5 hours, or about 30 times longer than that of the natural hormone. About 32% of the drug is excreted unchanged in the urine. In patients requiring dialysis, clearance is reduced to about one-half that of normal subjects. Thus, dosage adjustments may be necessary in patients with severe renal failure. The effect of hepatic disease on the disposition of octreotide is unknown.¹

LEAH R. ZINDEL, R.Ph., Drug Information Specialist, Department of Pharmacy, University of Connecticut Health Center, Farmington, CT.

Clinical Trials

VIPomas

Most studies involving the use of octreotide for the symptomatic treatment of VIPomas, (ie, watery diarrhea syndrome or pancreatic cholera), involve single or small numbers of patients. Maton et al,⁴ for example, have reported the effectiveness of octreotide 100mcg twice daily in a 60-year-old woman who had pancreatic cholera due to a metastatic tumor. After the first day of treatment, bowel movements were reduced from 10 to two per day. Fecal loss of potassium dropped from 348 mmol/day to less than 25 mmol/day. Within the first three hours of treatment, plasma concentrations of VIP decreased by 49%, neurotensin by 89%, and motilin by 75%. The patient was maintained on this therapy for three months without any apparent adverse effects until she died from other causes related to her illness.

Similarly, Ch'ng and colleagues⁵ treated five patients with pancreatic endocrine tumors, including two with VIPomas, two with glucagonomas and one with a tumor producing growth hormone releasing factor. In all patients, a 50mcg subcutaneous dose of octreotide twice daily produced a drop in the tumor-related hormone to at least 60% of basal value. In the two patients with VIPomas, mean VIP concentrations dropped from 361pmol/L to 207pmol/L and from 120pmol/L to 60pmol/L. One patient was able to return to work full-time. After three to six months of treatment, increased tumor related hormone concentrations and mild deterioration in symptom control were noted. This was reversed by increasing the dose to 100mcg twice daily.

In another case,⁶ 50 mcg of octreotide administered once daily produced dramatic results in a 75-year-old woman with VIPoma, including a reduction in the number and size of secondary tumors in the liver. Frequency and volume of watery diarrhea, which had been 15 times and two liters per day, were effectively reduced, and a persistent hypokalemia improved. There was a progressive decrease in plasma VIP, as well as pancreatic polypeptide (PP) and neurotensin. The patient gained 5kg and remained controlled on octreotide for nine months.

Carcinoid Syndrome

The efficacy of octreotide in the treatment of malignant carcinoid syndrome was evaluated in 25 patients with histologically proven metastatic carcinoid tumors and the carcinoid syndrome.⁷ The dosage of octreotide given was 150mcg subcutaneously three times daily. Of the 24 patients who had reported flushing prior to the initiation of therapy, seven patients reported complete relief, 12 reported at least a 50% reduction in symptoms, and three had minor but definite relief. Relief from flushing generally occurred within a few hours of the first dose of octreotide. All 25 patients had had diarrhea prior to therapy. After the initiation of octreotide, four patients had complete relief, 15 patients had at least a 50% reduc-

tion in the number of bowel movements, and three patients had definite, but less dramatic relief. There was a gradual return of both symptoms to near pretreatment levels over the course of three to 15 months. Adverse drug effects were mild and included transient hyperglycemia and steatorrhea.

Less successful was a French study,⁸ involving 18 patients, nine of whom suffered from carcinoid syndrome. Octreotide 100 mcg administered SC twice daily produced only a partial or inconsistent response in these patients. Of the nine patients, four experienced a near normalization of bowel frequency and stool consistency, two patients showed a lesser but definite improvement, and three patients did not improve at all. Only three patients noted a partial improvement in flushing, one a slight improvement, all others had no change in flushing.

The six responsive patients were continued on chronic therapy for up to 13 months. Two of the six patients showed no clear benefit and therapy was discontinued. Partial clinical improvement persisted for the remaining four patients. The dosage of octreotide was increased to 200mcg to 300mcg twice daily, as needed, to maintain clinical benefit.

Despite the lack of uniformity in response, urinary 5-hydroxyindole acetic acid (5-HIAA) was lowered in all cases, although it never reached normal levels. In six patients who had increased levels of plasma substance P-like immunoreactivity, levels normalized partially in three patients, and completely in the remaining three. The authors attributed their spotty success to a lack of aggressiveness in dosing.

Acromegaly

Although octreotide is not yet indicated for the treatment of acromegaly, a number of studies have shown it to be of benefit in the treatment of these patients.^{9,10} Most recently, for example, Barkan et al⁹ treated 15 patients with active acromegaly with octreotide 50 to 250mcg every six to eight hours for up to 21 months. Eight of these patients had been treated previously; seven patients were newly diagnosed. GH suppression was achieved in all but two patients, one of whom showed improvement with the addition of bromocriptine. In addition to the reduction in GH levels, administration of octreotide resulted in the normalization of plasma somatomedin-C (SM-C) values and significant shrinkage of pituitary tumors in seven previously untreated and two previously treated patients. Of the 13 responding patients, significant clinical changes occurred within the first several days of therapy, with diminution of facial features, reduction of hand volume, and a disappearance of hand paresthesias, excess perspiration, headache, and fatigue. The addition of bromocriptine in one non responding patient led to similar clinical improvement.

Interestingly, the investigators found that a single subcutaneous injection of octreotide suppressed GH for approximately eight hours, causing them to recommend

that the drug be given three times a day. Additionally, they suggested that previous studies might have proved more successful had the dosage been pushed more aggressively; in one patient dosing was titrated upward from 50mcg every eight hours to 250mcg every six hours to achieve adequate GH control.

In another study by Lamberts et al¹⁰ ten patients with acromegaly received octreotide 200 to 300 mcg, given in two to three divided doses daily for an average of 64 weeks. Amelioration of clinical symptoms was noted within the first six weeks of therapy. SM-C values were normalized in five patients and the mean 24-hour GH concentration fell from 44.0 ± 3.4 mcg/L before treatment to 7.8 ± 4 mcg/L at the end of the therapy. There was some evidence that octreotide induced tumor shrinkage; concentrations of SM-C and GH were significantly lower after 18 months to two years of treatment than after six to twelve months of therapy. Slight shrinkage of the pituitary tumor was observed by computerized tomography in three of the six patients in whom this could be evaluated.

This study also compared octreotide 50mcg with bromocriptine 2.5mg in 17 acromegalic patients. Octreotide suppressed plasma GH levels after two to six hours to 5mcg/l or less in 10 of 17 patients, whereas bromocriptine did the same in only five patients. A combination of both drugs significantly suppressed plasma GH levels in two of three patients who were unresponsive to either compound alone.

Other Unapproved Uses

Octreotide has been used experimentally with some success in the treatment of various secretory tumors including gastrinomas, glucagonomas, and insulinomas.^{5,8,11,12} It has also been shown useful as an adjuvant to the treatment of small-bowel fistula in postoperative patients¹³ and in the management unresolved AIDS-related cryptosporidium diarrhea.¹⁴ Preliminary studies have additionally shown that octreotide substantially reduces bleeding in patients with esophageal varices.¹⁵

Precautions/Adverse Reactions

Octreotide, like the natural hormone somatostatin, may be associated with cholelithiasis. Patients on extended therapy should have periodic ultrasound evaluation of the gall bladder and bile ducts.

Because octreotide alters the balance between the counter-regulatory hormones insulin, glucagon, and GH, hypo- or hyperglycemia may result from drug use. Patients should be appropriately monitored and treated. Similarly, because levels of T₄ fell in one octreotide-treated patient, thyroid function should be monitored.¹

Adverse reactions to octreotide are of mild to moderate severity and of short duration. They most commonly include nausea, injection site pain, diarrhea, abdominal pain or discomfort, and vomiting. From 1% to 3% of patients also experienced weakness, headache, dizziness, fatigue, flushing, fat malabsorption, hyperglyce-

mia, hypoglycemia, edema, or injection site wheal.¹

Drug Interactions

While no definitive interaction has been described between octreotide and the following agents it seems likely that the dosage of any drug that affects glycemic states, such as sulfonureas, insulin, diazoxide, and beta blockers, as well as the dosage of any drug that affects fluid and electrolyte balance, could require adjustment following the introduction of octreotide.

Similarly, octreotide has been associated with alterations in nutrient absorption and could therefore theoretically effect the absorption of any orally administered drug. Indeed, a single case of a transplant rejection episode in a patient treated with cyclosporine has been attributed to poor absorption of the drug secondary to octreotide usage.¹

Administration and Dosage

Although octreotide can be given by IV bolus injection under emergency conditions, the drug is generally given subcutaneously beginning with 50mcg once or twice daily. Thereafter, the dosage should be increased gradually, as the patient's needs and tolerance indicate, and divided between two and three doses a day.

In clinical studies the median daily maintenance dose of octreotide to control the symptoms of carcinoid tumors was approximately 450mcg. The dosage ranged, however, from 50mcg to 1500mcg per day. For controlling the symptoms of VIPomas, dosages of 200 to 300mcg in two to four divided doses are recommended during the initial two weeks of therapy; however doses from 150mcg to 750mcg have been used. Generally, doses above 450mcg per day are not required.¹

Availability and Cost

Octreotide is available in 1ml ampules containing 0.05mg, 0.1mg, or 0.5mg of drug. The cost to our institution is as follows:

<u>Strength</u>	<u>Cost per ampule¹⁶</u>
0.05mg/ml	\$ 3.60
0.1mg/ml	6.60
0.5mg/ml	28.50

Patient home administration starter kits are also available.

Formulary Considerations

The data available on octreotide are difficult to assess. Although the drug has a number of physiologic effects and numerous potential therapeutic applications, the pool of individuals for whom octreotide could prove beneficial is small. It is therefore unlikely that it could be tested in a large enough group to provide meaningful statistical evaluation. Further trials appear to be necessary to clarify dosing issues.

Nonetheless, octreotide represents an advance in the treatment of VIPomas and carcinoid syndrome and shows promise in the treatment of acromegaly and a

number of other disease states. It is a pharmacologically unique agent, perhaps the first of a whole new class of drugs, the peptidomimetics.³ While octreotide may find limited use in the smaller community hospital, most tertiary care hospitals will want to stock this drug for those patients for whom it is uniquely suited.

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AROUND THE STATE

Roger Beck, M.D., President of the Connecticut State Medical Society, is shown congratulating **Peter R. Dodds, M.D.**, a Norwalk urologist, upon receiving the 1989 Dr. Melvin G. Magida Award. The Award has been presented annually since 1980 by The Richard and Hinda Rosenthal Foundation in cooperation with the Fairfield County Medical Association to commend a young Fairfield County physician for "demonstrated notable capability in patient treatment and care."

This citation was presented to Dr. Dodds at the FCMA Semi-Annual Meeting on 12 October 1989 in Greenwich. The 38-year-old urologist, who resides in Wilton, was recommended for the Award by a committee of the Norwalk Hospital medical staff. In a letter from Albert V. Burke, M.D., Norwalk Hospital's chief of staff, Dr. Dodds was commended as "a competent, caring and personable young physician" who has assumed a leadership role among his colleagues at the hospital.

Dr. Dodds joined Urology Associates of Norwalk in 1983 after having completed residencies in surgery and urology at Yale-New Haven Hospital. He received his medical degree in 1977 from Columbia University College of Physicians and Surgeons. His undergraduate work was done at East Stroudsburg University of Pennsylvania. He became board certified in urology in 1985.

In addition to his serving as secretary of the Norwalk
(*Around the State continues on p. 754*)



Hospital medical staff, he is a representative to the Hospital Staff Section of the Connecticut State Medical Society.

He and his wife, Joan, have two children, Jessica and Tyler. As a family they are involved with the Guiding Eye Program in raising a Labrador retriever which ultimately will be turned over to the Program for additional training with a blind person.

According to Richard L. Rosenthal, chairman and past chief executive officer of the Citizens Utilities Company, "Dr. Magida was an example of a practitioner who rendered care and treatment with a genuine concern for his patients, their families, the community in which he practiced, and was highly respected by his colleagues."

Six Poems

RITA IOVINO, M.D.

Morning

so soft the cerulean sky
the dew moist upon the hills
the muses never sang so sweet...

Gone are the night time fears
The phantoms that fester feverishly
Plaguing the calmness of the mind
Gone are the demons of despair
That dwell in the Hades of one's soul
Casting spells of reality
Chanting poems of inequity
Brief glimpses of lightning truths
Be gone!

so quiet the earth awakens
Apollo smiles with his deception
come and drink, poor dreamer
this nectar of oblivion...

Old Age

I remember white taffeta
That albino caterpillars spin
The Brandenburg concerto was playing
And my veil was being tossed in the wind
I remember the powder on my cheek being damp
1921, and he took me in his arms for the bridal kiss
Where are they now?
The daughters that I labored for two August days
They would not come
And now they shove me out
The white orderlies restrain me with sheets
My lunch lies lying in my lap in the heat
I cry for nothing
I cry for everything
This is the winter season of my garden
I see two angels guard my marble tomb.

Incantations

Piña colada
Votive candle burning white
I see my dreams in aromatic haze
My life a burnt wick
Cry, cry
And no one shall hear you
The incense say prayers
To deaf saints
No Hail Marys will catch the ears
Of the gods that bestow crippled minds
To young women
My church is full of yellow lights
Intercessions where none is given
Go to Hell
And I'll burn my piña colada candle
At the wake.

Black Rhino

You wear your death upon your head
An aphrodisiac and a silver dagger
You wear Ethiopia's charms on your body
And court the African plains with your hoofs
They butcher you so that they can love
And love of money becomes obsessive in the heat
Your cries echo as the sun sets
It sets red on the black rhino.

RITA IOVINO, M.D., Clinical Instructor, Department of Pediatrics,
University of Connecticut School of Medicine, Farmington.

The Trade

Little Otterro
Like magnets
Your dark Mexican eyes
Drew us to your crib
Black as coals
They glittered like some black diamonds
That the Spanish conquistadors
Had forgotten to plunder
But
Within the darkened mines
That your ancestors dug
A glint of silver shone
Called retinoblastoma
And so my little Mexican
You must give up one of your diamonds
In exchange for life
A trade
That your Indian ancestors
Would have been proud of.

Death of a Baby

A precious bundle of unfulfilled dreams
Lost to a land where I cannot go
Where are you now little soul?
Where is the path you travel?
You did not drop breadcrumbs along the way
I cannot answer to your cry
Little spirit, comfort my aching heart
The pine trees sway in answer to the wind
But you do not answer
The waterlilies swirl in the currents of the stream
But you do not stir
The nightingale echoes through the darkening forest
But you do not cry
Where are you now little soul?
Your spirit hovers over the mountains
Oh, rest my baby
Sleep in the arms of the yellow dawn.

Support for the National Leadership Commission on Health Care

Last month *Connecticut Medicine* published the "Executive Summary, Report of the National Leadership Commission on Health Care." We have recently learned that the American College of Physicians, with 65,000 members, has lent their support to this general approach. Dr. John R. Ball, Executive Vice President wrote the following supportive letter to Dr. Simmons:

September 29, 1989

Henry E. Simmons, MD, MPH, FACP
President
National Leadership Commission on Health Care
555 13th Street, NW
Washington, DC 20004

Dear Dr. Simmons:

The American College of Physicians has long been concerned with the health needs of those in our society who do not have access to adequate health services. Like The National Leadership Commission on Health Care, we believe a comprehensive reform of the nation's health system is necessary if we are to be able to meet the three-part goal of ready access, reasonable cost, and appropriate quality.

The College is supportive of the approach of the Commission and wants to participate with you as you move the Commission's proposals forward. Although there is some concern within the College over the particular financing mechanisms proposed by the Commission, we are nevertheless in consonance with the general approach, and especially applaud the manner in which the Commission has addressed the need for the development of medical practice guidelines and the need for malpractice reform.

We congratulate the Commission for its leadership in emphasizing the need for a systemic approach, and look forward to working with you.

Sincerely yours,

Philadelphia, PA

John R. Ball, MD, JD, FACP

To Smell the Rose Above the Mould

A Dynamic Challenge for the Aging

As a senior citizen, one sometimes tires of hearing and reading so much about dying, be it with dignity, with euthanasia, or with a living will. Living with gusto and interest is not an age-limited state of being. Rather it is an opportunity remaining only to be seized: *Carpe diem!*

Thesis on Aging

Some types of life span are more limited than others, as William Osler explained in his valedictory address of 22 February 1905 at John Hopkins after being named Regius Professor at Oxford. In referring especially to university life, he admitted to two fixed ideas: The first, "the comparative uselessness of men above forty years of age"; the second, "the uselessness of men above sixty years of age." He then drew attention to Anthony Trollope's novel, *The Fixed Period*, in which is described "...a college into which at sixty, men retired for a year of contemplation before a peaceful departure by chloroform." Both statements were extensively elaborated upon in his address but taken out of context by some of his listeners; it was no surprise that newspapers ran headlines the next day: "OSLER RECOMMENDS CHLOROFORM AT SIXTY," and the word Oslerize briefly entered the language.

Cushing in his biography of Osler records this event in true context and concludes: "It required no great degree of intelligence to distinguish between the serious and the jocular in what Osler said...no one's feelings, even were he past life's meridian, should have been ruffled in the slightest." Some time later, during his Harvard tenure, Cushing, himself, was instrumental in establishing age 63 for the retirement of professors of surgery. Both men continued to lead productive lives well past mandated retirement as did other historical figures. Churchill for one remained an inspiring and witty leader well into his 80s. Chancellor Konrad Adenauer was another. At age 87, *Der Alte* was still guiding Germany into postwar recovery.

Socially Nebulous

Retirement and death, both subject to some postponement, are inevitable. But what of the interval between these two events? Within the constraints of physical and scholastic parameters of the aging group, what advice can physicians and our medical association offer people who have entered this enviable though socially nebulous period of life? The dynamic challenge is to encourage people to remain physically and mentally active, emotionally involved, giving as well as receiving, and above all, playing and working with enthusiasm. The goal is to

be independent, active, and self-reliant.

Sweden, Denmark, and Finland have answered the challenge by helping the elderly to achieve these goals with dignity and security.² Their system, which permits the elderly to live in their homes or in sheltered integrated housing projects, is called "open care." Home care is provided by "home helpers," paid workers who come to the home and provide that level of assistance required by the older person. General activities are provided across diverse areas of interests. Dignity and respect is encouraged by addressing these elderly by their full names rather than by the patronizing use of first names. Their system did not sprout full-grown from the brow of some legislator, but evolved over a period of 50 years. In this country private developers have already entered this field of congregate, protected housing for the independent elderly. Its mention here is not to offer a quick solution to our growing problem of old age care but to offer an alternative to nursing, custodial, or convalescent home care.

Such an alternative, be it in congregate adult housing or, for the more fortunate, continued family life, can shift the current preoccupation with dying with dignity to living to the end with dignity. Again, our example is Sir William Osler,¹ who after 65 continued to work, to write, and to lecture. A most distinguished honor for a physician came in his election to the presidency of the British Classical Association. It was after attendance at a meeting of the Association of British Physicians that he wrote to a friend: "...my Pneumococcus struck in..." There followed a succession of bouts with bronchopneumonia. When colleagues many years his junior were called upon to manage his disease, about which the Chief knew so much more, he always put them at ease with reassurance and irrepressible humor. Finally, in one of these relapses *H. influenzae* was the organism identified. He expressed premonitions about the fatal nature of such pneumonias in people in their seventies and yet, between distressing paroxysms of coughing, he was able to write to a dear friend in a hand now barely legible, "and on most days I can smell the rose above the mould." So the goal for the aging is to live with physical, mental, and emotional vigor so that they, too, in their last days might smell the rose above the mould.

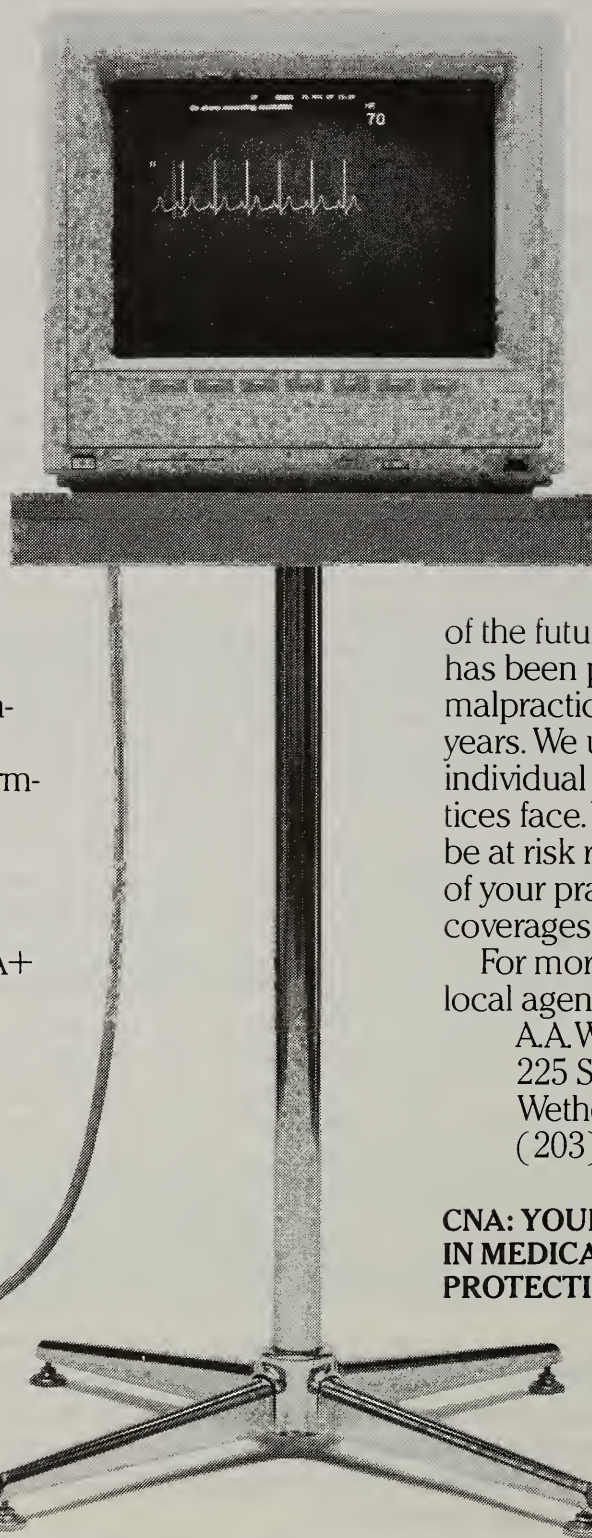
Lycurgus M. Davey, M.D.

New Haven

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Semi-Annual Meeting of the CSMS House of Delegates

Report of the President

November 15, 1989



The activities of the Connecticut State Medical Society go on at a fast and seemingly accelerating pace. Your officers, the Council, and Council Committees are involved in addressing a bewildering array of issues and challenges. Only the superb support of Executive Director, Timothy B. Norbeck, Associate Executive Director, Josephine P. Lindquist, and the entire headquarters organization prevents complete chaos.

State Society programs, CMIC (Connecticut Medical Insurance Company) and M.D. Health Plan are highly successful. The Group Purchasing Plan, offered only recently, already has contracted with over 500 medical practices and is a service you may wish to consider.

CMIC now has a membership of 2,475 physicians in its professional liability program. Finances are strong. Premium decreases in the range of 1.5% to 6.2% depending on class and amount of coverage have been announced for 1990. M.D.

Health Plan, the Society sponsored IPA/HMO, has exceeded projections and expects to have 25,000 members by year end. For each of the past three quarters the plan has reported a small profit. Enrollees in the plan can choose among, 2,200 participating physicians. The Group Purchasing Plan offers through the Society office discounts to physicians on a wide variety of equipment, supplies, and services.

The Council presided over by Chairman Joseph C. Czarsty, M.D., meets regularly between meetings of this House of Delegates to set policy and conduct the business of the Society. The many committees and Society officers then implement those policies. Your handbook contains a record of Committee accomplishments. Especially noteworthy are the activities of two Committees. The CME Committee, chaired by Marvin Garrell, M.D., which reviews hospital medical education programs to determine eligibility for accreditation was itself reviewed by the National Accreditation Council for Continuing Medical Education (ACCME) for recognition to continue as Connecticut's CME accreditation agency. Many physician volunteers devote considerable amounts of time making site visits to review various hospitals. The Legislative Committee, Howard Wetstone, M.D., Chairman, has met several times this fall to prepare for the 1990 legislative session. Ably assisted by Kyle L. Ballou, Esq., Associate Director for Government Affairs, and the Society's lobbyists, Sullivan and LeShane, the Committee has considered a long list of possible legislative issues and recommended to the Council several policy positions which were approved. This Committee continues to meet and work with specialty societies seeking to develop a unified medical profession approach to the legislature and its committees.

Your officers have been busy. Representing the Society I have attended six county association meetings this fall and was everywhere impressed with the vitality of these organizations. Their many notable programs and achievements are not adequately reported at the state level. Thanks to Joseph Zeppieri, M.D., and the New London County Medical Association, the State Society participated as a cosponsor with the Worker's Compensation Commission in celebrating their 75th Anniversary with a two-day seminar attended by about 450 health care professionals. Additional informal small group meetings with Commissioner John Arcudi to discuss mutual problems are scheduled. Four of us met with Commissioner Mary Ellen Klinck and Deputy Commissioner Marcia Bell of the Department of Aging to discuss CONNMAP (Successor to the State Society's voluntary courtesy card program) and mandatory assignment. Other meetings have taken me, as your representative, out of state to places as widely scattered as Albany, NY, Dixville Notch, NH, and Newport, RI. It has been an exciting six months but, no doubt, the toughest challenges will come when the legislature convenes in January.

Roger S. Beck, M.D.
President

DOCTORS: YOU'RE GAINING ON THE LOSSES.

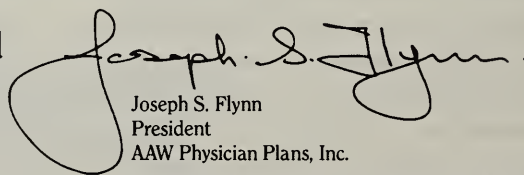
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Messages in Bottles

ROBERT U. MASSEY, M.D.

During a recent dinner meeting, mostly doctors, the talk turned to books; one suddenly and defiantly announced, "I've never read *David Copperfield*!"

"I've never read *Bleak House*, I answered, "or Dante all the way through, although I've started five or six times; same thing with Joyce's *Ulysses*."

"No one's ever read that, although they think they have," someone else remarked, "You often have the feeling that you've read some book although you suspect you really haven't. Most people who talk about this or that best seller may have seen the book review. A year or so later they think they've read the book, and will say so shamelessly."

Last month our director of admissions had the idea that we should offer a list of books to our incoming class for them to read during the summer before they start medical school, books that would introduce them to their new profession, maybe tell them something about the traditions of medicine, its ethos rather than the problems everybody says it has. I have been briefly surprised to find that medical school applicants have rarely read the books I think they should have, forgetting that *Arrowsmith*, *The Citadel*, and *Burma Surgeon* are two or three generations in the past, and forgetting also that, past or present, books have never been part of their lives.

Some faculty have suggested serious sociohistorical works like Paul Starr's *The Social Transformation of American Medicine*, or Kenneth Ludmerer's *Learning to Heal*, heavy going indeed for the last free summer. My vote would be for biography, Harvey Cushing's *The Life of Sir William Osler*, for example, but then that is almost 1,400 pages, only a few hundred shorter than *War and Peace*; the *Osler* can come later, and should.

There are some works that are deep in the center of our Western civilization, that unite us at some critical level of our consciousness, and yet may be represented only by fragments somewhere in the cortices of some of us and most of our students. I am uneasy when no one recognizes that "the valley of the shadow of death" is from somewhere in the Psalms, or when faces are blank at the mention of a Faustian wager or the wrath of Achilles. Maybe William Osler's list, or something like it, would be the place to start after all; doubtless it is old-fashioned,

reflecting "his love of the classics and the attitudes of the last century."¹

The "Bed-side Library for Medical Students" appeared first at the end of the 1904 edition of *Aequanimitas*; Osler intended it to assist the student "to get the education, if not of the scholar, at least of a gentleman."

- I. Old and New Testament.
- II. Shakespeare.
- III. Montaigne.
- IV. Plutarch's Lives.
- V. Marcus Aurelius
- VI. Epictetus.
- VII. *Religio Medici*
- VIII. *Don Quixote*
- IX. Emerson.
- X. Oliver Wendell Holmes—Breakfast Table Series

In a report on his survey of members of the American Osler Society, Robert Rakel noted that the Bible and Shakespeare were in third or fourth rank, with Osler's *Aequanimitas*, and Cushing's *Osler* coming in first and second. With the plan that Osler recommended, "Before going to sleep read for half an hour, and in the morning have a book open on your dressing table," I calculate that even a slow reader could get through the New Testament in a month, the entire Bible in six, and Shakespeare's plays in three or four, even leaving the dressing table free for *The New England Journal of Medicine*. More than a summer but less than a year.

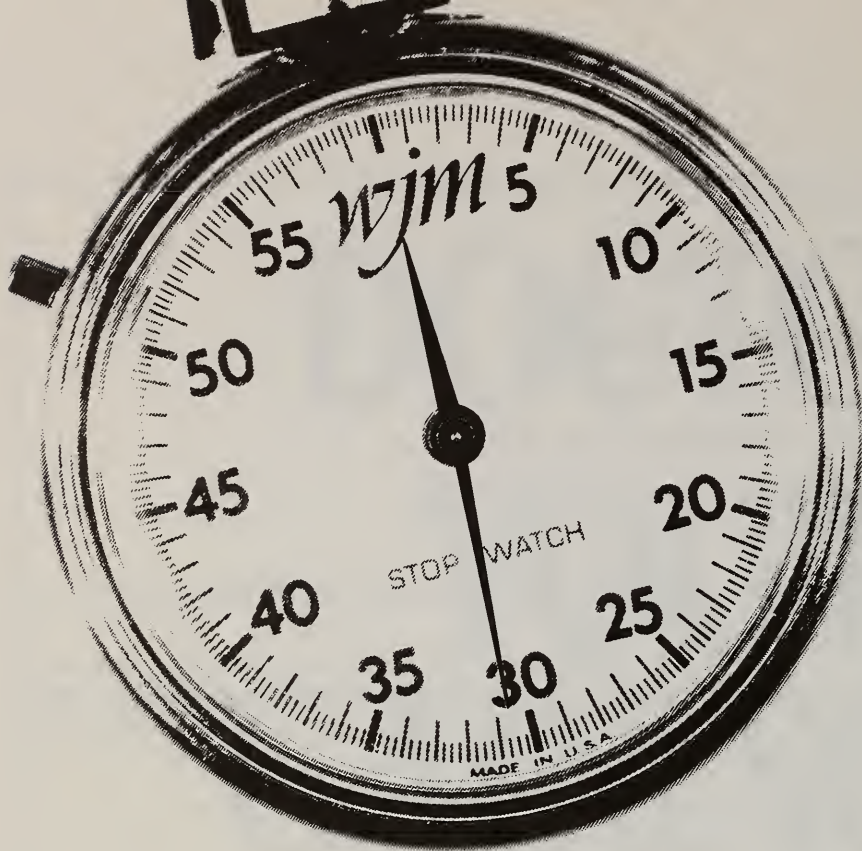
Osler's list suits me fine except for the last two authors who are planted so firmly in the nineteenth century; also I would suggest only selective reading in the three classical authors, and I would substitute the *Iliad* and the *Odyssey* for the two moderns. Goethe's *Faust* or Dante's *Divine Comedy* could be taken for honors.

One reason we read, perhaps the chief one, according to the novelist Walker Percy, is because we are searching for messages in bottles; all of us are castaways on an island hoping for word from the mainland. Now and then these messages show up in *Peanuts*, but chances are they came first from somewhere in those ten or eleven books. Anyway, *Peanuts*, the introduction to clinical medicine, and even cell biology are more fun if you know all that ahead of time, or are lucky enough to come upon it later.

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ROBERT U. MASSEY, M.D., Professor, Division of Humanistic Studies in Medicine, Department of Community Medicine and Health Care, University of Connecticut School of Medicine, Farmington.



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50 Years Ago
From the *Journal of the Connecticut State Medical Society*
December 1939

Horace Wells Conquers Pain

A 95th Anniversary Review

By MAX E. SOIFER, D.D.S.*
Hartford, Conn

Two attempts^{1,2} have been made recently to malign and discredit the established reputation of Doctor Horace Wells, Dentist of Hartford, Connecticut, as the discoverer of anesthesia. These garbled half-truths and historical inaccuracies were answered by earlier writer.^{3,4,5,6,7,8} and again refuted in current periodical literature.^{9,10,11,12,13,14,15,16,17} On the occasion of the 95th anniversary of the discovery occurring December 11, 1939, it might be well to review briefly some highlights of the Wells story.

Horace Wells was born at Hartford, Windsor County, Vermont, on Jan. 21, 1815. After a broad and liberal education in select schools, he started the study of dentistry at Boston, Massachusetts, in the offices of established practitioners as was the custom of the time before the inauguration of formal dental school training. For two years he prepared himself for his chosen profession and in 1836 finished his training and opened an office for a brief period in Boston. Later that year he moved to Hartford, Connecticut, where within a short period of time he firmly established himself as an outstanding and capable member of the profession. He published in 1838, an illuminating essay¹⁸ which gained for him the respect and admiration of his professional confreres. Under his tutelage John M. Riggs and William T. G. Morton were given dental training during 1841-43. Both of these men later acquired fame in the profession. With Morton as a co-partner he opened another office in Boston to popularize one of his inventions for soldering teeth to dentures.

Witnessing an exhibition of "laughing gas" in Hartford given by Professor Gardiner Q. Colton on December 10, 1844, he visualized its application to dental and surgical operations for the relief of pain and arranged for a demonstration at his own office the following morning. Here on December 11, Horace Wells underwent the first

extraction of a tooth under nitrous oxide gas thus giving to suffering humanity the boon which had long been sought. On this memorable day, ninety-five years ago, anesthesia, was conceived, demonstrated and proclaimed by Wells. Together with Riggs he experimented both with nitrous oxide and ether, but on the advice of his associates he preferred the former as more suitable for short dental operations. The following month he visited Boston in order to lay his findings before the Medical Faculty there and to make his discovery "as free as the air we breathe." Unfortunately, due to his excitement at having to perform the dual role of anethetist and extractor, his demonstration was only partially successful and his patient did cry out, yet admitted afterwards that he felt no pain. Few of those present on this occasion really understood the manifestations of patients in this anesthetized state and therefore attempted to discredit Wells and his work. He returned, however, to Hartford and, except for brief periods during 1845 and 1846 when he was forced to relinquish his professional duties due to a physical ailment, Wells continued to administer the gas for dental and surgical operations up to the time of his death in 1848. He never, as has so often been claimed, abandoned either his profession or his favorite anesthetic.

Full recognition for his contribution came to his name from the Connecticut Legislature, the city, county and state medical and dental groups, the Medical Society of the State of New York, the Boston Gynecological Society, Parisian Medical Society, Spanish Odontological Society, American Medical and American Dental Associations, medical and dental professions of England and the International Dental Federation.^{13,15} Memorials have been preserved in Hartford, Chicago, Washington and Paris.¹⁵ Countless tributes have been paid him in litera-

ture.¹⁵ He remains, despite the assertions of other claimants, the recognized discoverer of anesthesia. This sentiment has been well expressed in a resolution received by his widow in 1873 from his professional confreres in England who declared: "The world is indebted to him not only for introduction of Nitrous Oxide as an Anesthetic but for having given that impetus to the study of Anesthesia which has resulted in the introduction of ether, chloroform and various other agents for affecting that object."

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AROUND THE STATE

(continued from page 744)

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For more information, call or write: Robert M. Jeresaty, M.D., Director, Section of Cardiology, Saint Francis Hospital and Medical Center, 114 Woodland Street, Hartford, CT 06105-1299, (203) 548-4820.

Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and abridgment), provided that they are submitted in duplicate, signed by all authors, typewritten in double spacing, and do not exceed 1½ pages of text (excluding references). They should not duplicate similar material being submitted or published elsewhere. Letters referring to a recent *Journal* article should be received within six weeks of the article's publication.

SURGERY BY NON-SURGEONS

To the Editor: I read with interest *Surgery by Non-Surgeons: Podiatric Surgery in Connecticut* written by John C. Russell, M.D. (*Connecticut Medicine*, September 1989). I am sure that this article, taken in its entirety, will be helpful to all of us involved in defining the role of the podiatric surgeon in Connecticut hospitals.

Several concepts mentioned in the article need to be explored from a little different perspective.

It is specious reasoning to relate the number of years of postgraduate training to a better standard of care. Podiatric medicine's specialized medical school education plus one to three years of surgical residency results in a far superior background in lower extremity biomechanics and foot surgery than a three-year general orthopedic residency. Interestingly, a number of orthopedic surgeons have enhanced their training by completing a podiatric surgery residency. Of further interest are the 1987 Part B Medicare Annual Data Studies (BMDD). These studies reveal that over 70% of forefoot surgeries were performed by D.P.M.s compared to under 24% by orthopedic surgeons and 56.9% of rearfoot surgeries were performed by D.P.M.s as compared to 32.5% for orthopedic surgeons.

In the hospital setting, surgical credentialing, privilege delineation, and quality assurance are conducted under the auspices of the chief of surgery. However, these activities are performed by members of each subspecialty division in accordance with JCAHO guidelines. In this regard, podiatric surgeons are no different than orthopedic surgeons. Would Dr. Russell have all of us do away with peer review?

While standard of care issues, quality assurance, and criteria for surgical procedures should transcend surgical subspecialties, this is not always the case.

Dr. Russell's article should be viewed as an opportunity to encourage dialogue between podiatric surgeons and other members of the hospital team.

Jeffrey F. Yale, D.P.M.

Chairman, Podiatry Division
Department of Surgery, Griffin Hospital
Derby

The above letter was referred to the author of the article in question, who offers the following reply:

To the Editor: The letter of Dr. Jeffrey P. Yale, D.P.M. in response to my article "Surgery by Non-Surgeons: Podiatric Surgery in Connecticut" (*Connecticut Medicine*, September, 1989) raises several interesting points. While I am sure that Dr. Yale would agree with the concept that specialization (in medicine or podiatry) has improved the quality of medical care during this century, Dr. Yale questions the concept that the number of years of postgraduate training translates to a better standard of care. To compare two years of postgraduate podiatric surgical training with the current four year requirement for general orthopedic residency programs is, in fact, an "apples and oranges" comparison. It would be of interest to know the actual numbers of orthopedic surgeons who have, in addition, completed podiatric surgery residency programs.

The statistics that Dr. Yale provides regarding the distribution of forefoot surgery between D.P.M.'s and orthopedic surgeons, as well as rear foot operations, cannot be evaluated without a specific listing of the kinds of procedures. How many of these procedures included toenail operations or other office procedures, or ankle procedures (outside the scope of podiatric practice in Connecticut)? The reasons for this distribution of procedures (access to podiatric and/or orthopedic services, patient preference, perceived or actual quality of care, etc.) can only be speculated. My purpose was to present one of several arguments usually stated within hospital medical staffs as to why there is not a need for podiatric surgical activity (i.e., that these services are already provided through their orthopedic departments), rather than to make a judgment as to the validity of this statement.

Dr. Yale's comments regarding the method of credentialing and privilege delineation are difficult to understand. As I am sure Dr. Yale is aware, the issue of peer review, particularly in view of the recent Patrick decision, has become a problem for all branches of medicine; for me as a hospital-based surgical chief, this is an area of on-going discussion and concern. The broadest possible participation of the medical and podiatry community should be encouraged for successful peer review. I do feel that the criteria for review for specific procedures should be uniform, whether they be done by an orthopedic surgeon or a podiatric surgeon, similar to the need for standardized indications and quality assurance criteria for facial plastic surgery, whether performed by a plastic surgeon, a general surgeon, an otolaryngologist, or an oral/maxillo/facial surgeon.

I am pleased that Dr. Yale has taken the time to respond to this article, and I hope that a frank dialogue between the medical and podiatric communities will continue.

John C. Russell, M.D.

Chief of Surgery,
New Britain General Hospital,
New Britain

LUDWIG JOSEPH PYRTEK, M.D.

1915 - 1989



Ludwig J. Pyrtek, M.D., an exemplary general surgeon at Hartford Hospital for 40 years, died of pancreatic cancer on 19 October 1989. Born in Hartford, the only child of Polish immigrants, "Joe" Pyrtek graduated from Hartford Public High School in 1933, spent a postgraduate year at Dean Academy and attended Dartmouth College, class of 1939. He attributed his work ethic and tenacity of purpose to the influence of his parents and to the inspiration of Coach Earl "Red" Blaik, then the football coach at Dartmouth. As a scholar-athlete, Pyrtek was encouraged by his Dartmouth mentors to change from a history major to pre-med. He completed the preclinical years at Dartmouth Medical School and obtained his M.D. from Rush Medical in Chicago in 1942.

Dr. Pyrtek took his internship at Hartford Hospital, 1942-43, followed by a two-year tour in the European theater for which he was awarded the Bronze Star. He then secured surgical training at Union Memorial Hospital in Baltimore and later as a fellow in surgery at the Lahey Clinic in Boston. His work with Dr. Lahey in thyroid and parathyroid surgery and with Dr. Richard B. Cattell in biliary and GI tract surgery was seminal in establishing these as areas of particular scholarly interest. Dr. Pyrtek returned to Hartford Hospital in 1949 and began his practice of general surgery which over a 40-year period involved 30 thousand patients. He performed a phenomenal number of surgical procedures in all areas of general surgery, published more than 25 contributions in the surgical literature, and played an active teaching role as well. He taught best at the bedside and in the operating theater where his relentless pursuit of excellence in patient care and surgical technique could be conveyed to his students one-on-one. Many of the residents in the Hartford Hospital surgical program collaborated with him on papers and presentations at local, regional and national meetings. All who left the program for their own surgical practices around the country were quick to realize the importance of Joe Pyrtek's teaching and example in the conduct of their own work.

Dr. Pyrtek was a member of the Connecticut Society of American Board Surgeons and of the New England Surgical Society where many of his clinical presentations were made. He was a Fellow of the American College of Surgeons and a member of the AMA.

He was on the consulting staff at the Veterans Administration Hospital in Newington, courtesy staff at St. Francis and Mt. Sinai Hospitals and adjunct associate professor of clinical surgery at Dartmouth Medical School. He was clinical professor of surgery at the University of Connecticut School of Medicine, and over the years made a firm commitment to his "Professor's Rounds" at the University of Connecticut Health Center.

Awards and public recognition were graciously, though often quietly, received by Dr. Pyrtek from Dean Academy, from Dartmouth College, from regional sportswriters, and from Hartford Hospital for his athletic, professional, and personal achievements of a lifetime. Most extraordinary to him and to his colleagues was the establishment at Hartford Hospital, in 1987, of the Ludwig J. Pyrtek Chair in Clinical Surgery. Spearheaded by a devoted friend and former patient, substantial funds were raised for the Pyrtek Chair among patients, friends, and colleagues. It is a fitting tribute to Joe Pyrtek that the yield from this fund is to be devoted to the enhancement of surgical education at Hartford Hospital on into the 21st century.

Dr. Pyrtek and his wife Mary (Folette) were married during his medical school days in Chicago. Their relationship was one founded and sustained on love, trust, and mutual support of each other's busy, work-filled lives. The breaking of this bond by Mary's death earlier this year was a crushing blow to him. He remained, however, valiant in his grief, and valiant in his tolerance of his final illness, ever diligent in the care of his patients and devoted to the craft of surgery which he performed so well.

Hartford

H. David Crombie, Jr., M.D.

From the Executive Director's Office

SUMMARY OF PROCEEDINGS CSMS HOUSE OF DELEGATES—SEMI-ANNUAL MEETING Ramada Inn, North Haven—November 15, 1989

Reports and Resolutions

The House of Delegates received reports from the President, the Council, the AMA Delegation, the Executive Director, Connecticut Medical Political Action Committee (COMPAC), Connecticut Medical Management, Inc. (CMMI) and from M.D Health Plan. Recommendations and resolutions were also received from the Council, county associations and individual delegates.

Principal Actions Taken

- (a) **Report of the President**, Roger S. Beck, M.D., Hartford: The House voted to accept the report of the President, which included information on State Society Programs, CMIC update, activities of CSMS committees, and his attendance at the various county association meetings. The full text of his report appears in the President's Page in this issue of *Connecticut Medicine*.
- (b) **Report of the Council**, Joseph C. Czarsty, M.D., Oakville: The House voted to accept the report of the Chairman of the Council, which reviewed the activities of the Council since the last meeting of the House of Delegates. Minutes of the interim Council meetings have already been published in *Connecticut Medicine*. Special emphasis was placed on CMMI-CMIC activities, legislative activities and the 1990 Budget. The action taken on the Council's recommendation appears elsewhere in this Summary.
- (c) **Report of the AMA Delegation**, Stewart J. Petrie, M.D., Ansonia: The House voted to receive the report of the AMA Delegation, as information, which included a review of the AMA action on covering the uninsured, expenditure targets (ET's), uncompensated care and professional liability.
- (d) **Report of the Executive Director**, Mr. Timothy B. Norbeck: The House voted to receive the report, as information, and voted that it be published in *Connecticut Medicine*. The report included an in-depth review of the facts influencing the rising health care costs. The full report will appear in a future issue of *Connecticut Medicine*.
- (e) **Report of the Connecticut Medical Political Action Committee (COMPAC)**: Patrick J. Concannon, M.D., Middletown, Chairman, stressed the importance of physicians becoming active participants in the political process and pointed out that political action can be much more expensive to watch than

to join. The House voted to receive the report as information.

- (f) **Report of Connecticut Medical Management, Inc. (CMMI)**: Mehdi S. Eslami, M.D., Waterbury, Chairman, stated that CMIC celebrated its fifth anniversary on October 1, 1989, that there was a net gain in enrollment of 100 physicians over the previous year and that the CMIC has announced a premium decrease for its members effective January 1, 1990. The report also included data on CMIC Risk Management course, Finances and Claims. The House voted to receive the report as information.
- (g) **Report of M.D. Health Plan**: Vincent J. Catrini, M.D., Middletown, presented a report on the current and proposed status of the Plan. It included information on the financial performance of the Plan, enrollment statistics, and projected enrollment growth. Also reported were some of the Plan's major accomplishments which included the following: First Connecticut HMO to offer Life, Disability and AD&D insurance coverage, First Connecticut HMO to offer employer self-funded managed care program known as MedCHOICE HealthPlan, First Connecticut HMO to institute Age/Sex Rated Premium Program opening opportunities for small employer groups to join the HMO, Largest physician network (CSMS-IPA membership 2,200). The House voted to receive the report as information.
- (h) **Budget for 1990**: The House voted to approve the budget for 1990, as prepared and recommended by the Council, and that the dues remain at \$300.00.
- (i) **Resolution on Health Care Financing Authority (HCFA) Regulations**: (Introduced by Litchfield County Medical Association—Joel A. Danisi, M.D.) It was voted to support the intent of the resolution which reads:

"RESOLVED, that the Connecticut State Medical Society strongly recommends the study of the method of screening and weighted severity level scoring method of peer review and seeks the assistance and support of the American Medical Association."

It was further voted to express concern about the point system and referred the resolution to the Council for its consideration with particular attention for rephrasing.

(j) **Resolution on Medicaid Funding** (Proposed by Eugene H. Corley, M.D. and submitted under the sponsorship of the Fairfield County Medical Association.) It was voted to approve the resolution as amended by the House and reads as follows:

“RESOLVED, that the Connecticut State Medical Society reaffirm its policy to encourage Connecticut Physicians to continue to treat Medicaid patients, and be it further

RESOLVED, that the Connecticut State Medical Society lobby the State Legislature for adequate funding, so that we may continue to improve Medicaid services.”

(k) **Resolution on Humane Use of Animals in Medical Research** (Presented by Daniel W. Doctor, M.D., on behalf of the Norwalk Medical Society, and introduced by the Fairfield County Medical Association) It was voted to approve the resolution, as follows:

“RESOLVED, that the Connecticut State Medical Society affirms and supports the ethical and humane use of animals in medical research, development and education.”

AWARDS

**CSMS Past Service Awards to
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Guy W. Van Syckle, M.D., Danbury	
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Delegate to AMA,	1979-1988

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Alternate Delegate to AMA	1986-1988
Frank K. Abbot, M.D., Middletown	
Delegate to AMA	1981-1988
Vincent J. Catrini, M.D., Middletown	
Delegate to AMA	1988-1989
Robert J. Chmielecki, M.D., Bristol	
Alternate Delegate to AMA	1988-1989

COUNCILORS

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Litchfield County

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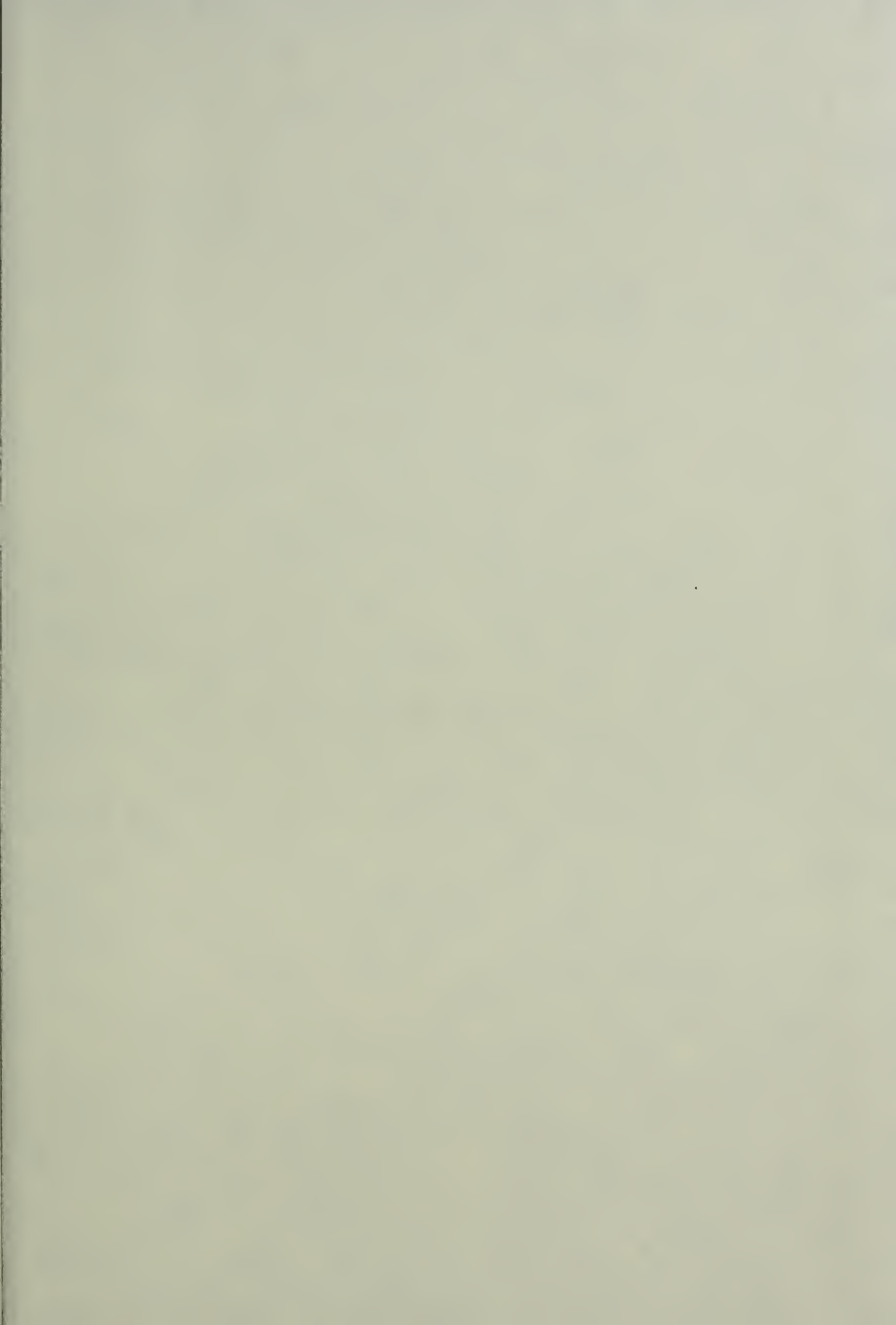
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